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Koch et al.

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(54) **PORTABLE INFUSION PUMP**

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(73) Assignee: **CAREBAY EUROPE LTD**, Sliema (MT)

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A61M 5/32 (2006.01)
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CPC ***A61M 5/3204*** (2013.01); ***A61M 5/1424*** (2013.01); ***A61M 5/1454*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61M 2005/14256; A61M 2005/31518; A61M 2005/3247; A61M 5/1424;
(Continued)

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Primary Examiner — Quynh-Nhu H Vu
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(57) **ABSTRACT**

A medicament delivery device includes a housing with a compartment for a medicament container, an injection needle arranged to housing and connectable to the medicament container for delivering a dose of medicament, a manually operated activation mechanism, an actuation mechanism operably connected to the activation mechanism and configured to extend the injection needle, upon activation of the activation mechanism, from a first position inside the housing to a second position for penetrating a patient, a plunger rod in the housing configured to act on the medicament container for delivering a dose of medicament through the injection needle, a driver configured to acting on the plunger rod for delivering the dose, and a needle cover operably arranged in the housing between a position inside
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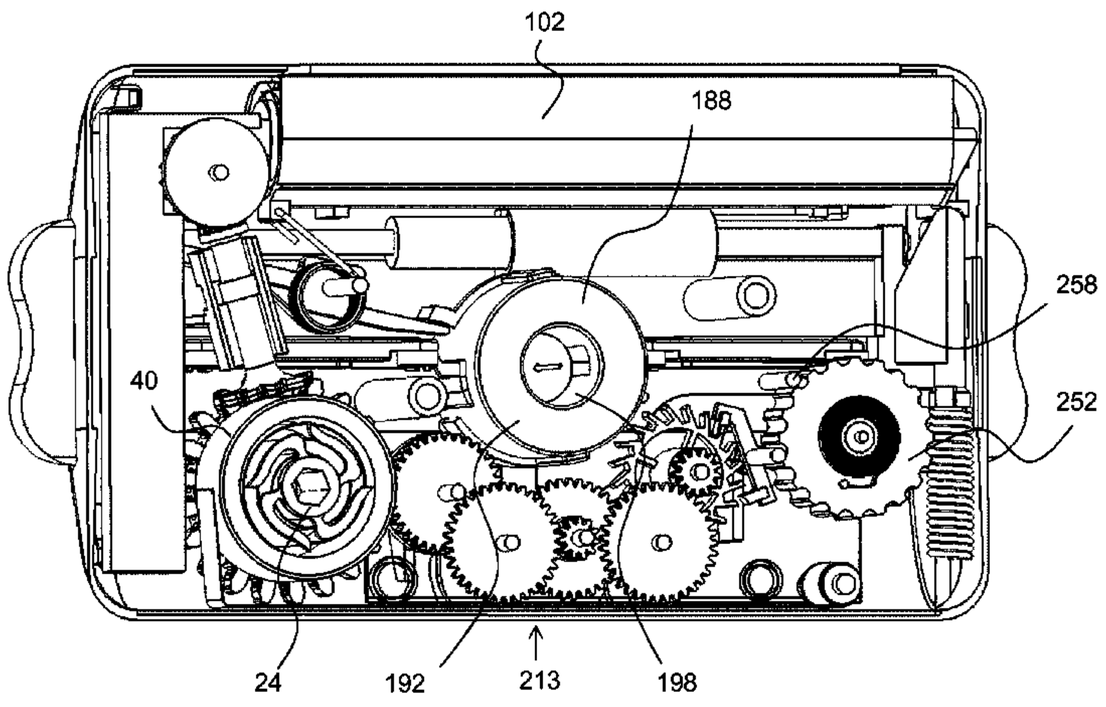

the housing and an extended position outside the housing for shielding the injection needle when the injection needle is in the second position.

15 Claims, 25 Drawing Sheets

(51) **Int. Cl.**

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A61M 5/142	(2006.01)
A61M 5/315	(2006.01)

(52) **U.S. Cl.**
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(58) **Field of Classification Search**
CPC A61M 5/14248; A61M 5/1454; A61M 5/14566; A61M 5/168; A61M 5/3204
See application file for complete search history.

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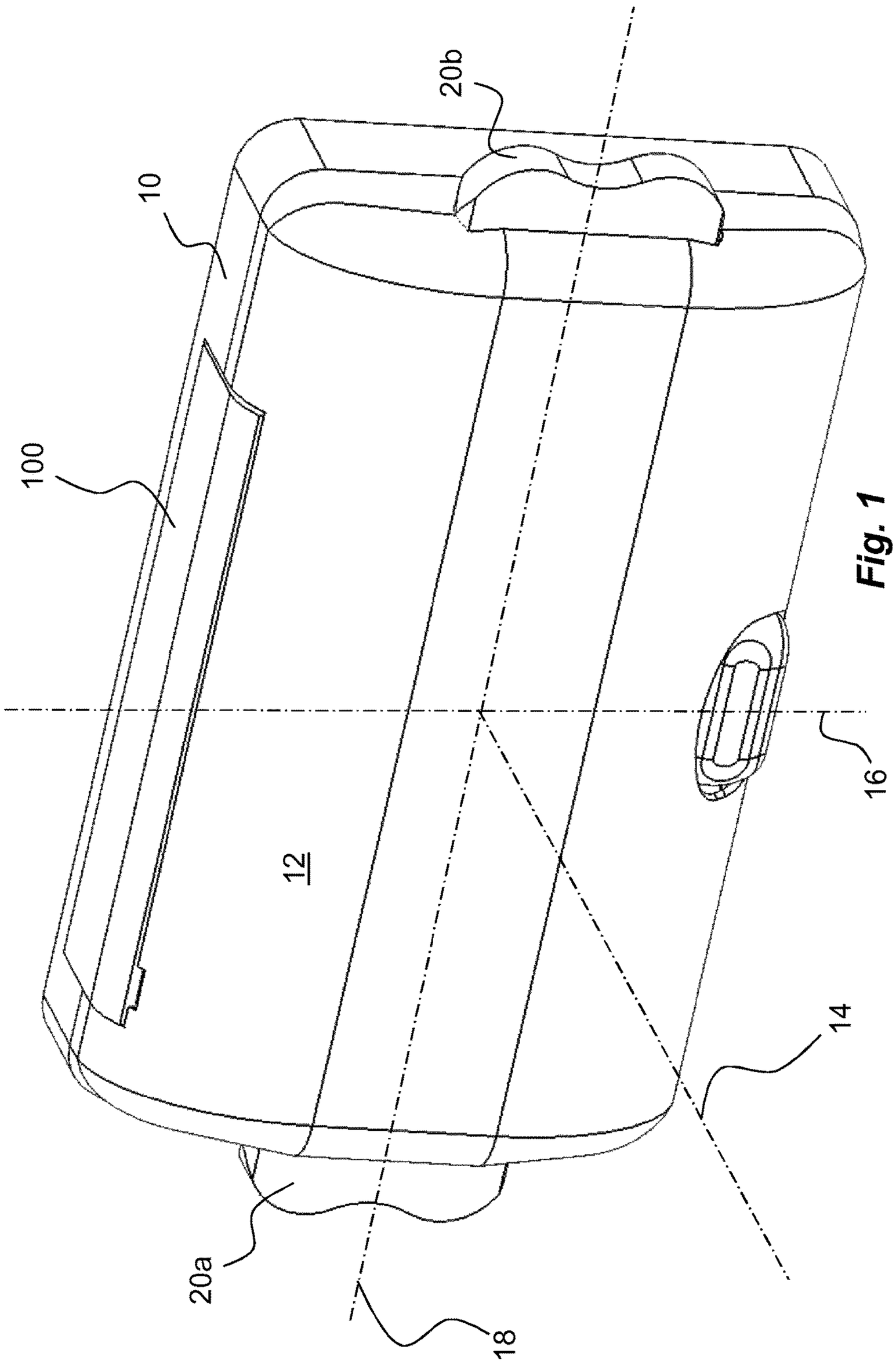

Fig. 1

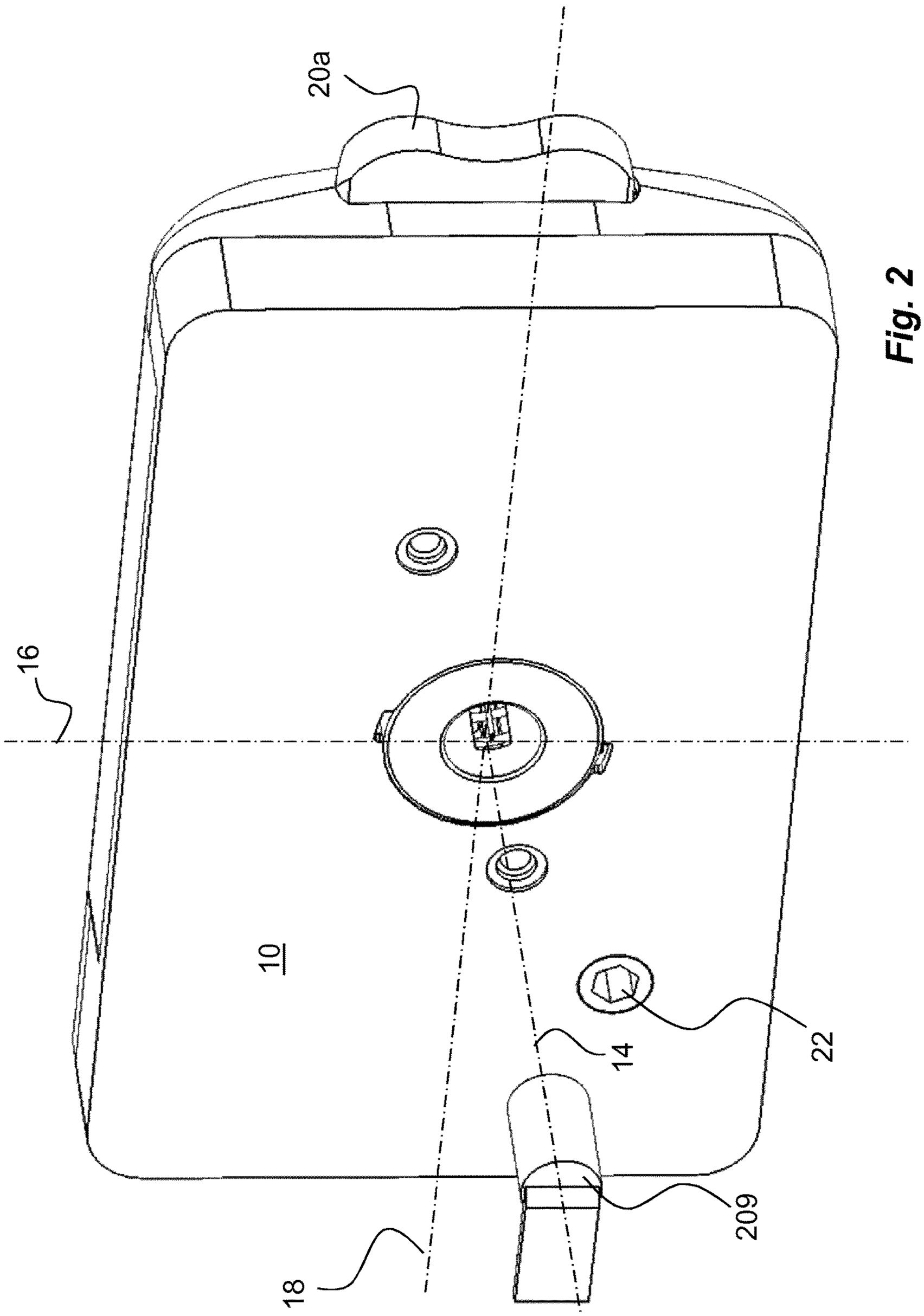

Fig. 2

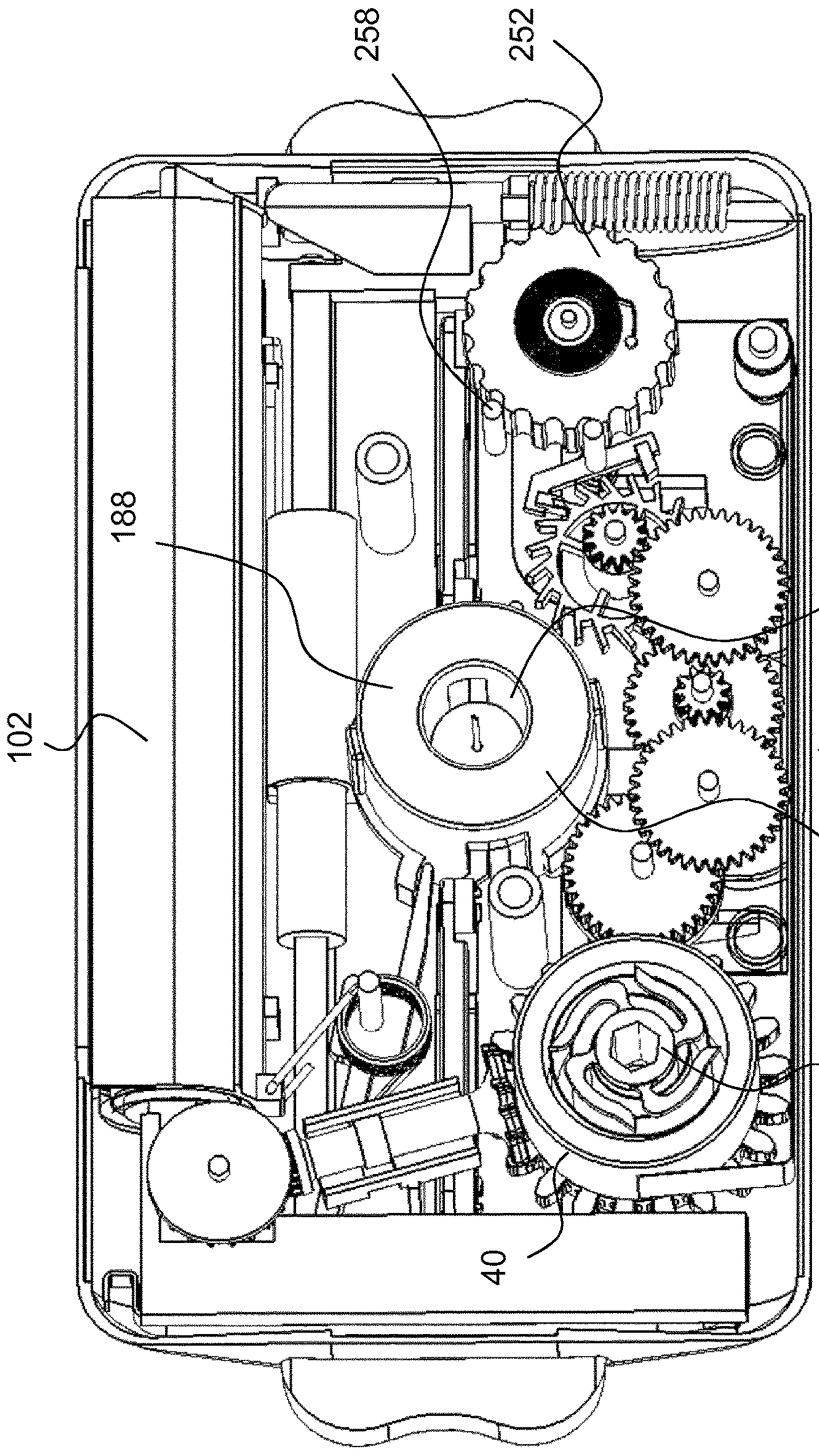

Fig. 3

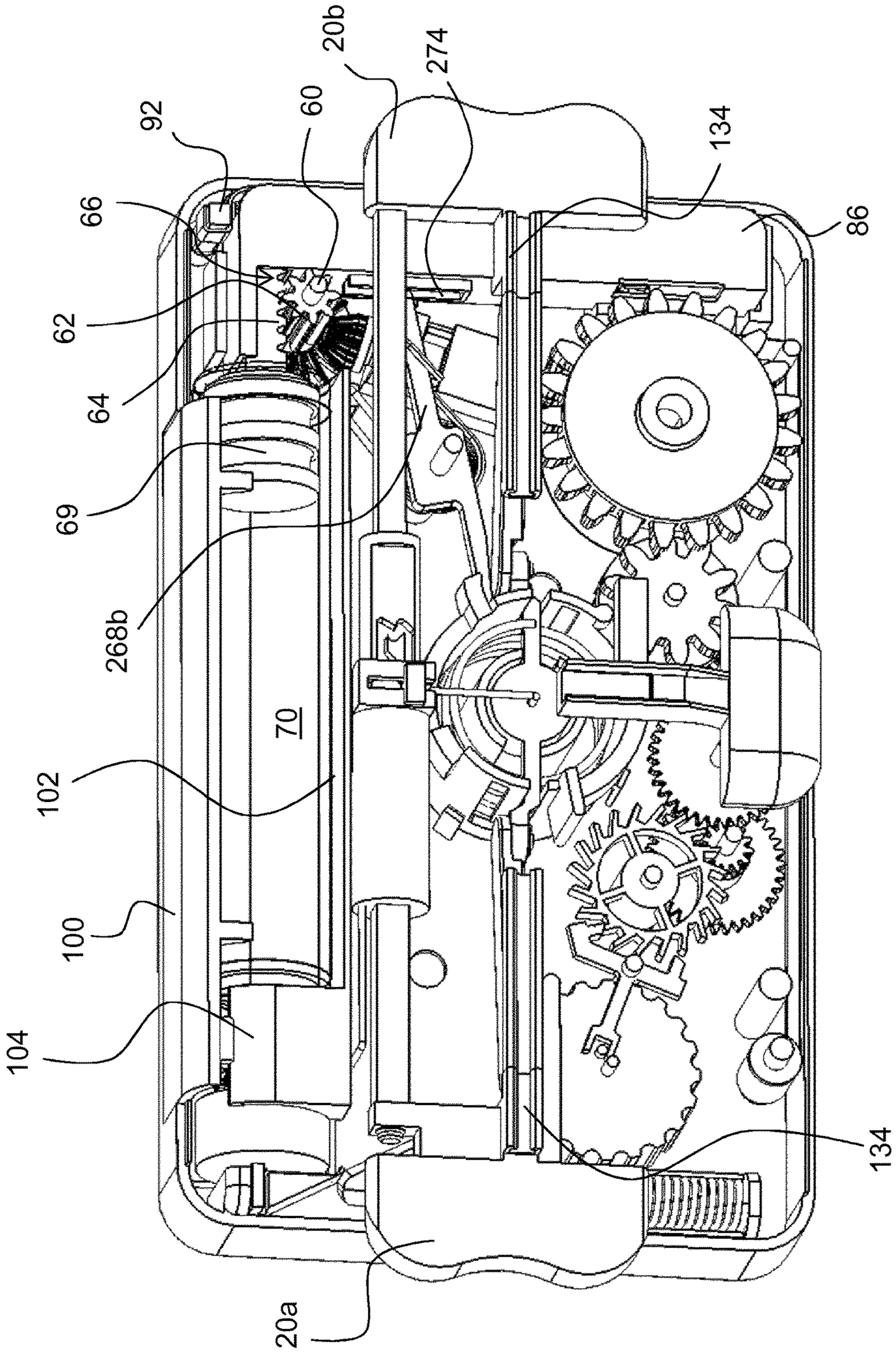

Fig. 4

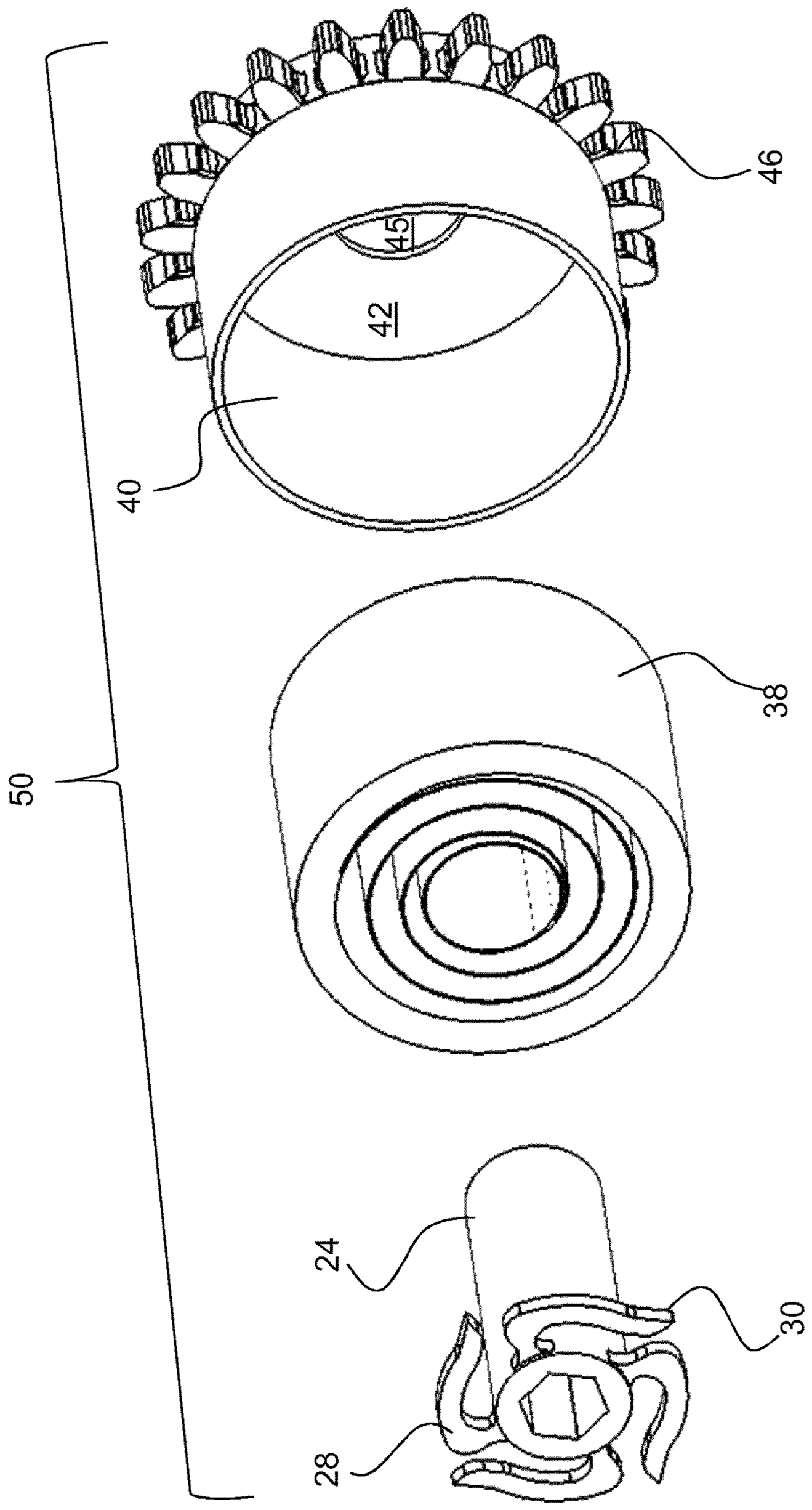

Fig. 5

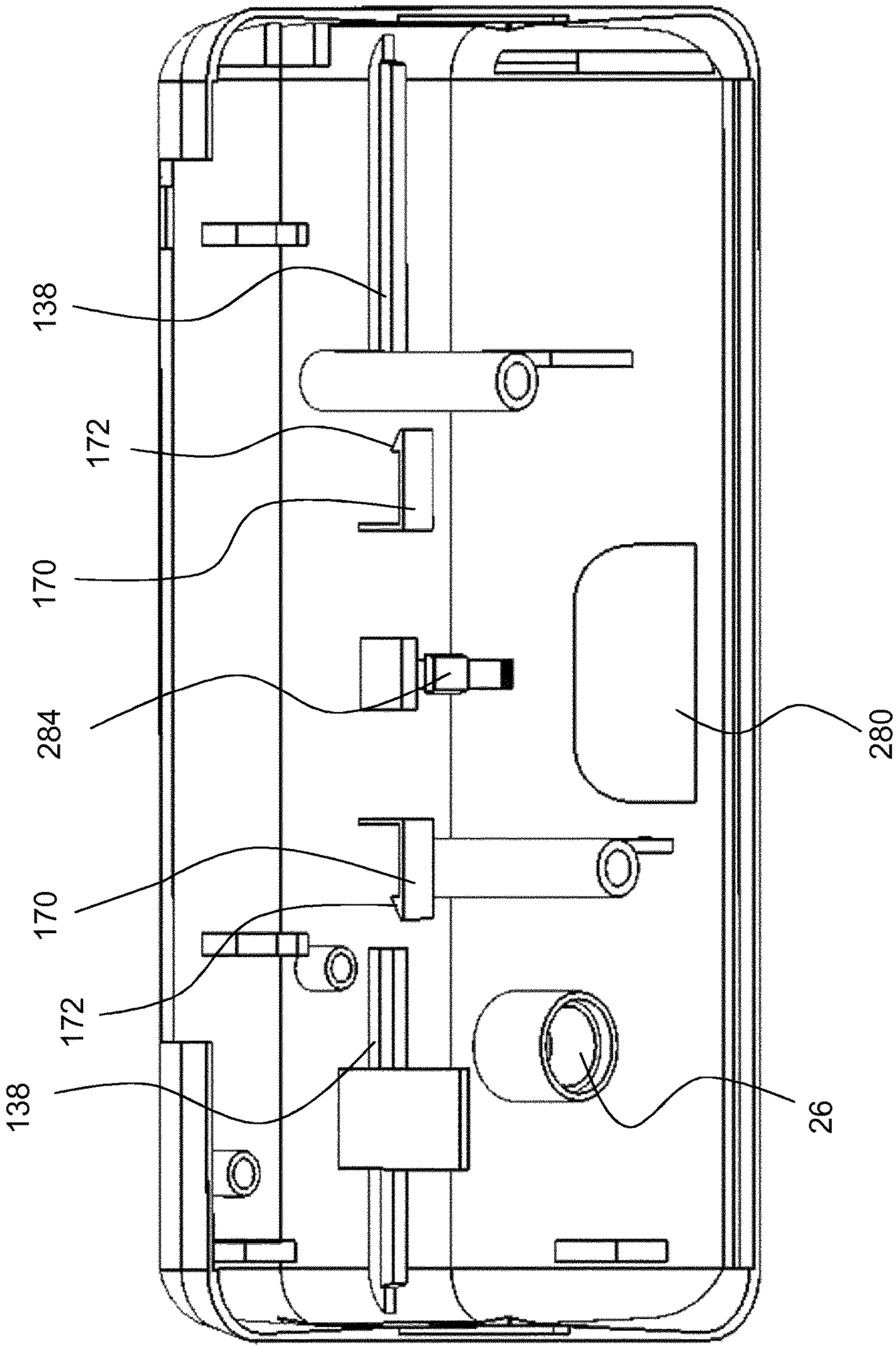

Fig. 6

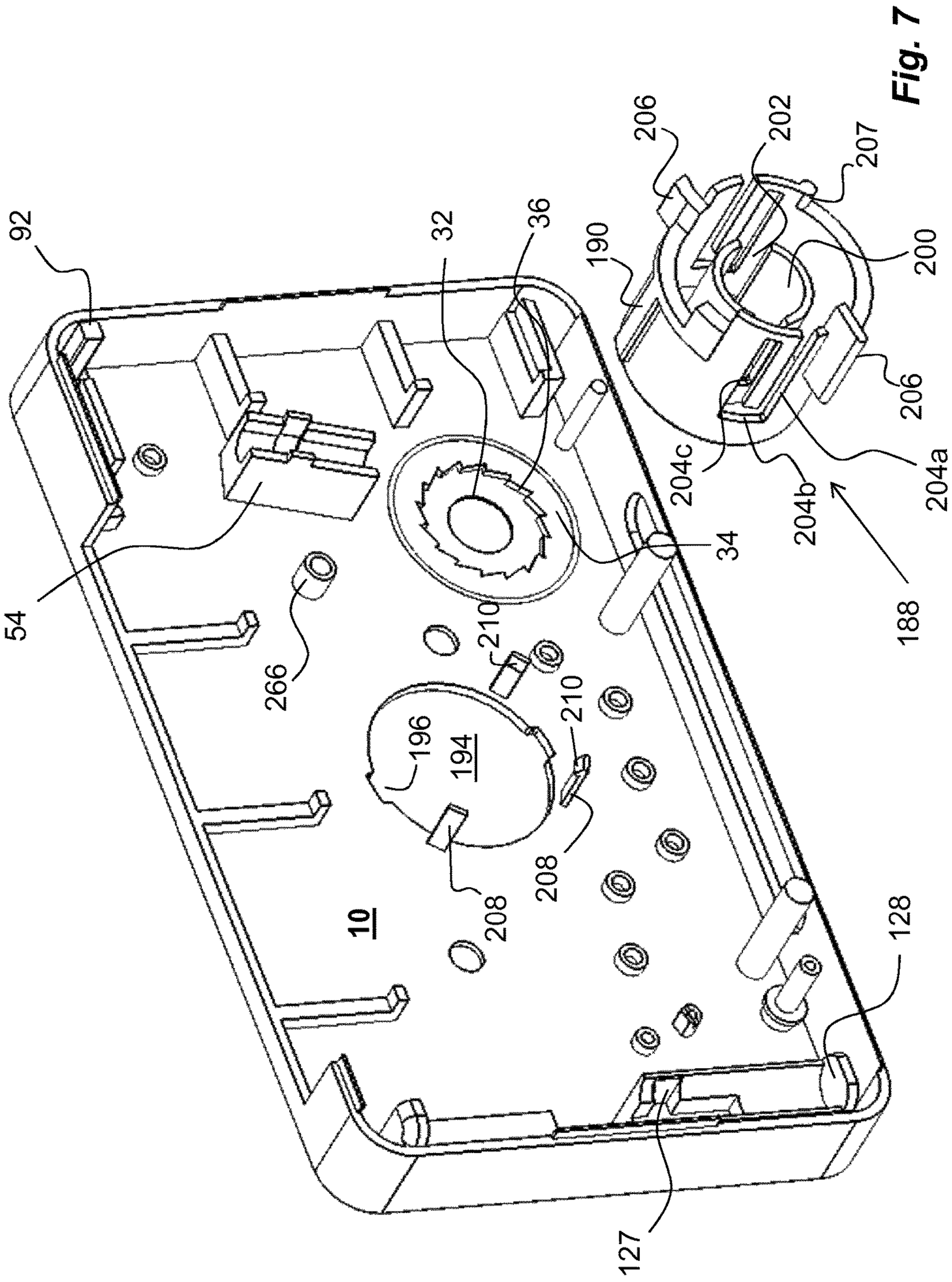
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Fig. 7

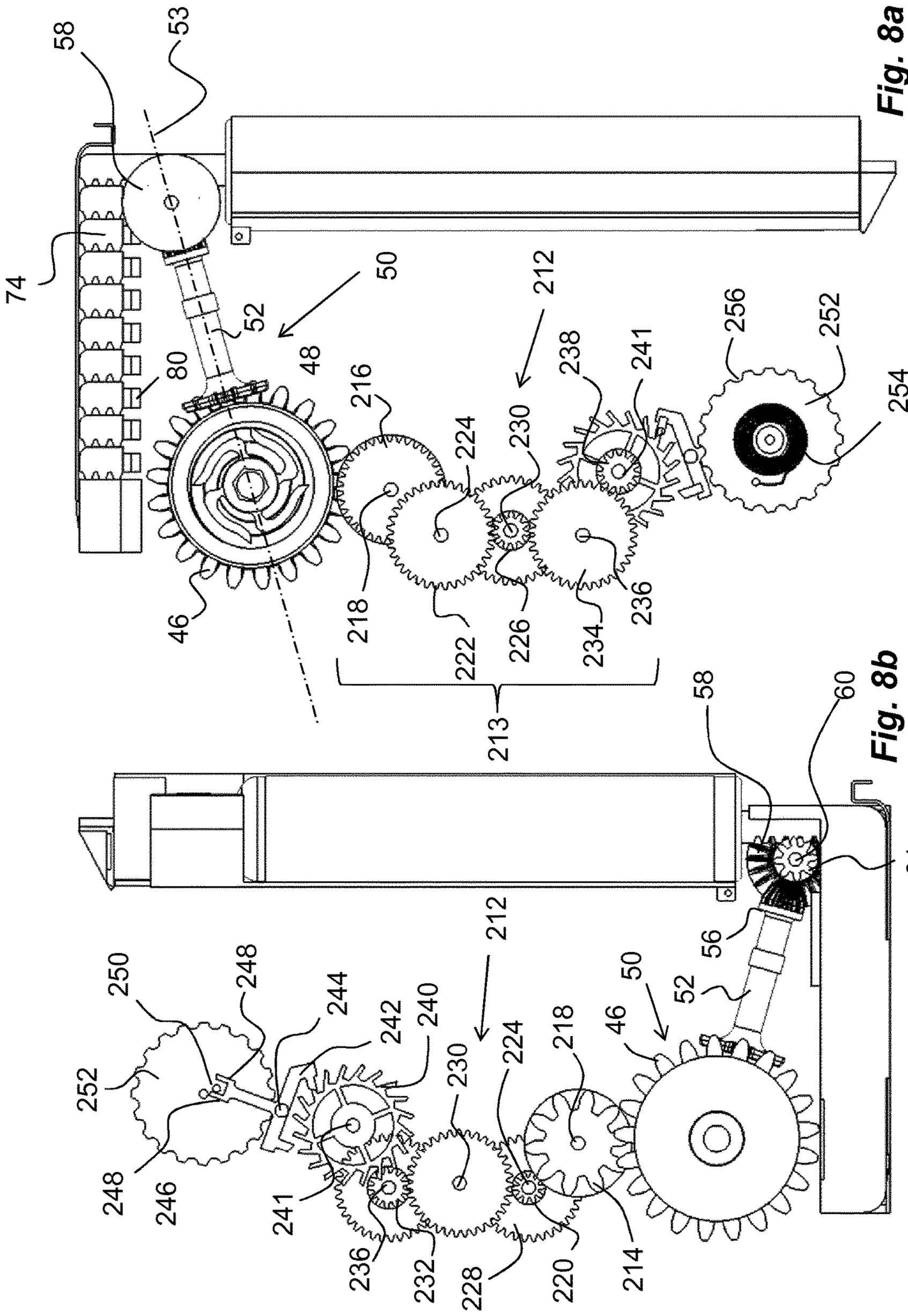
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Fig. 8a

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Fig. 8b

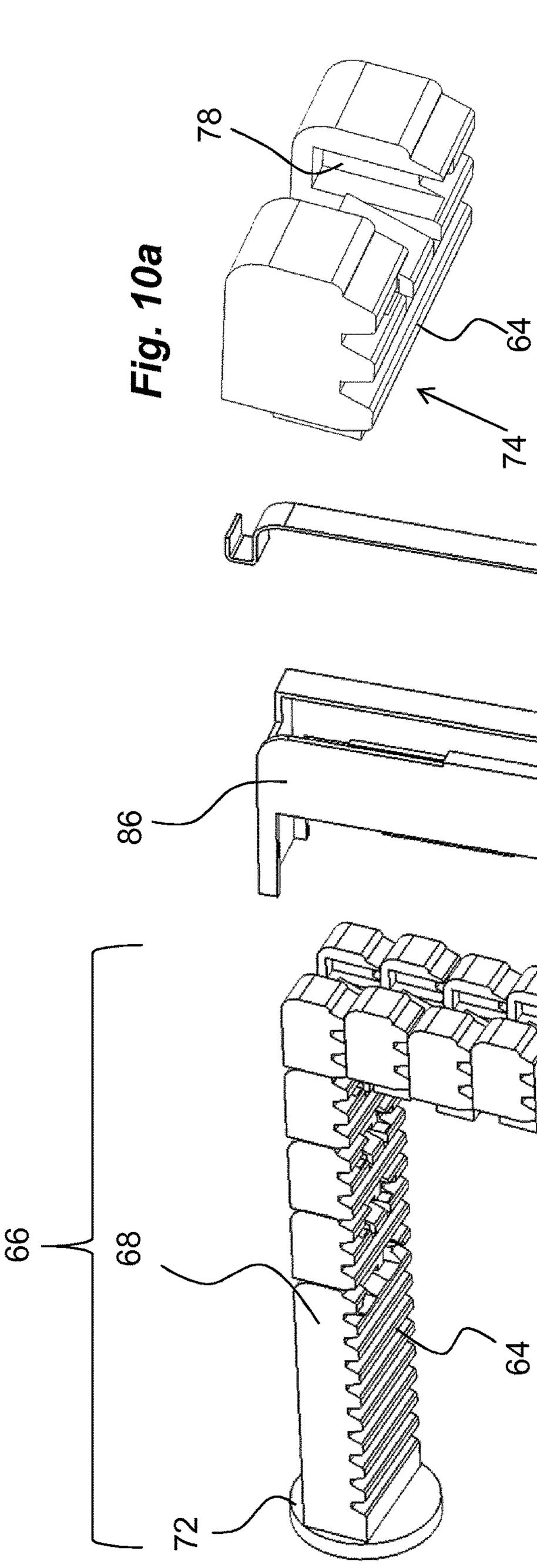

Fig. 10a

Fig. 10b

Fig. 9

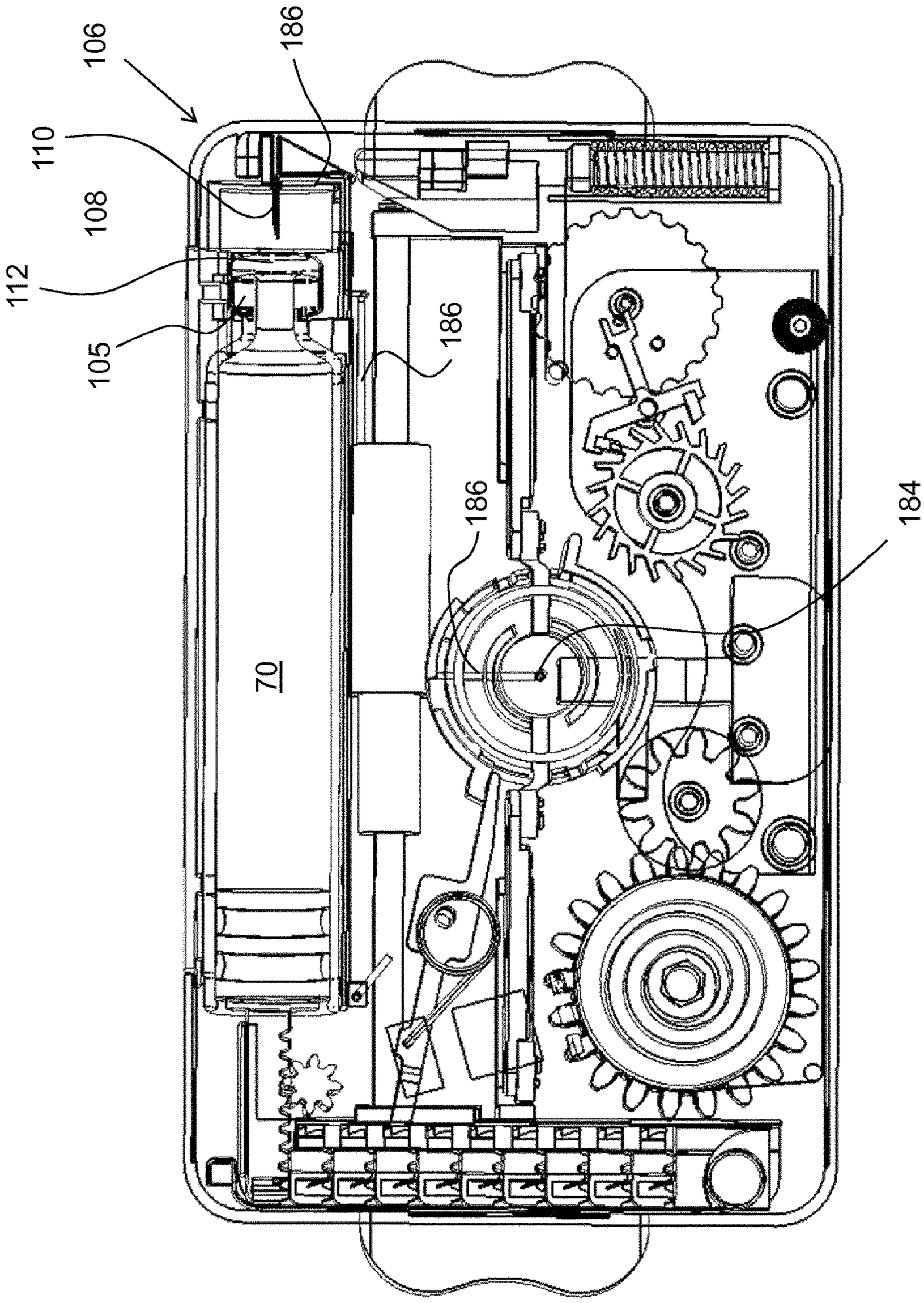

Fig. 11

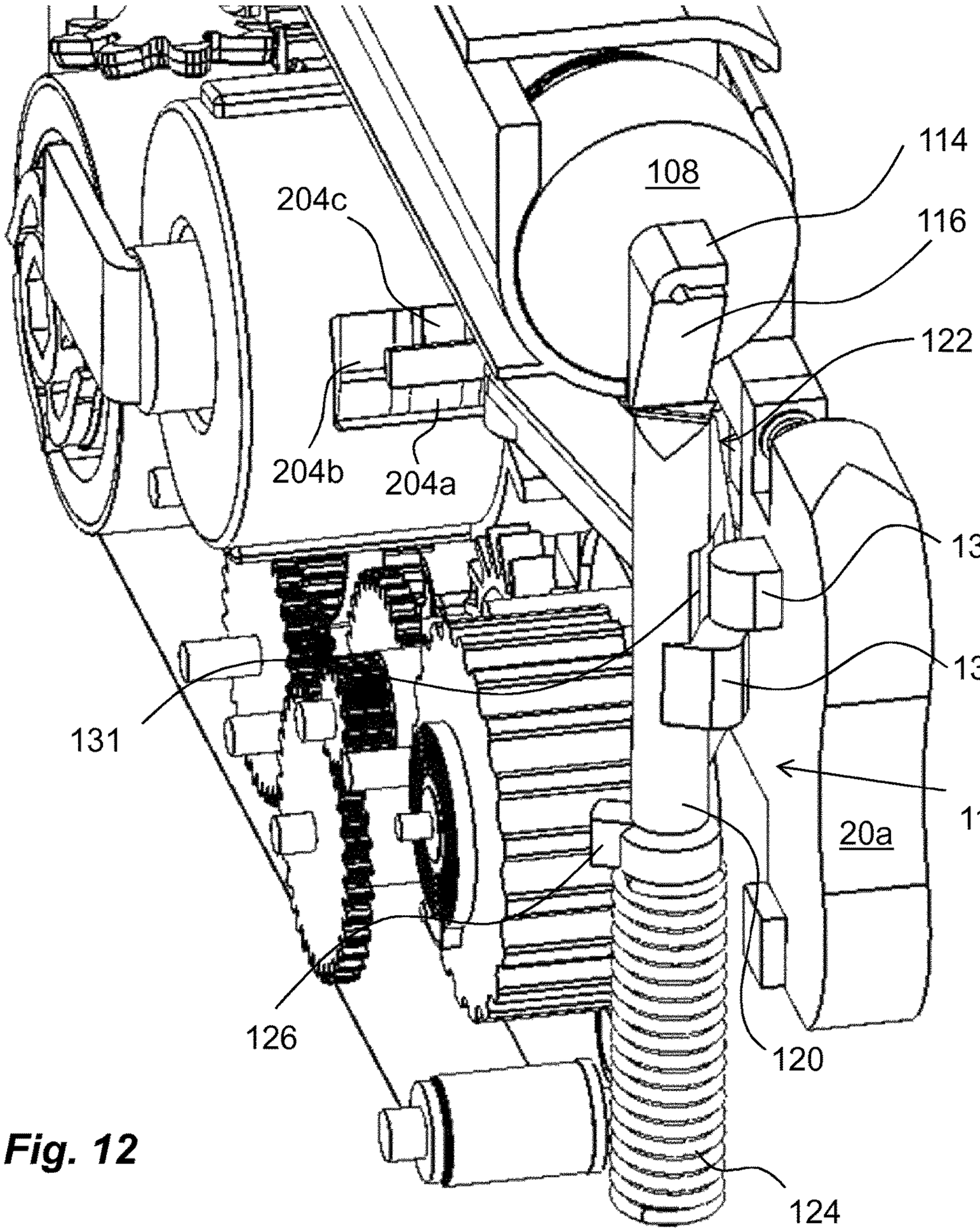

Fig. 12

Fig. 13

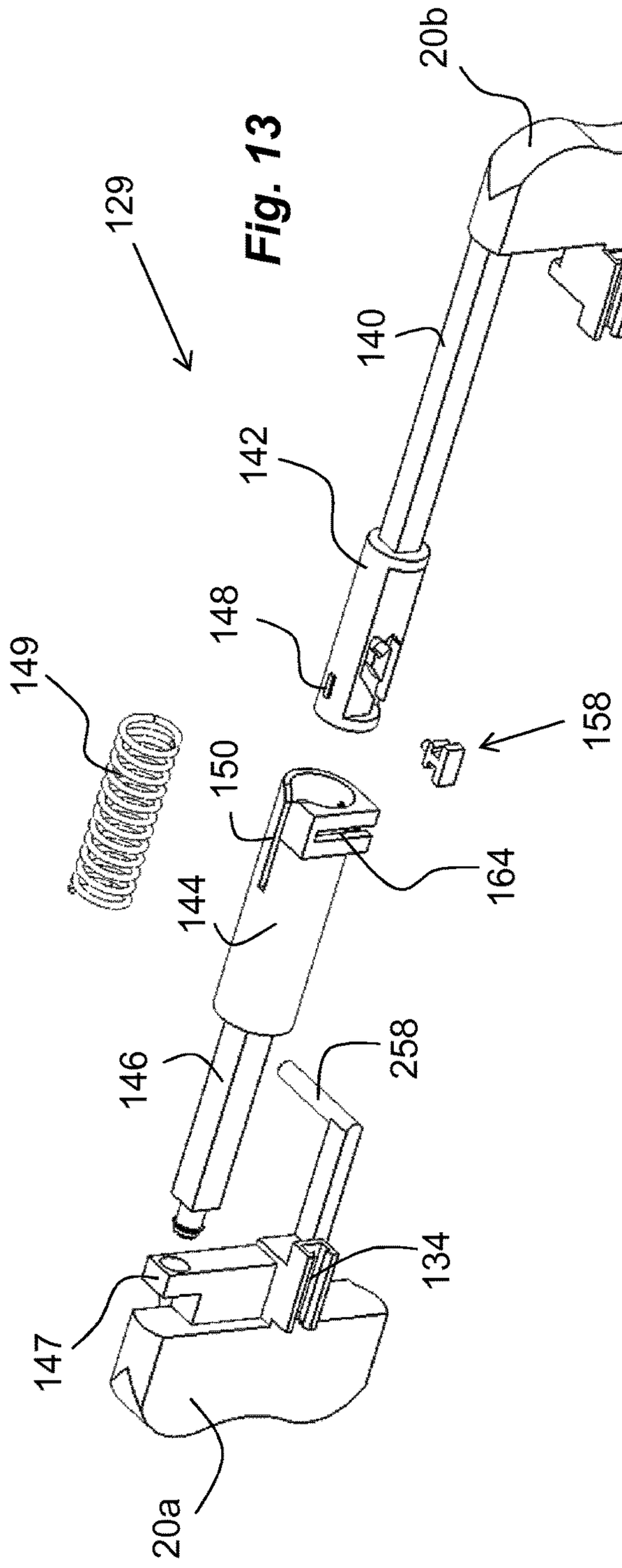
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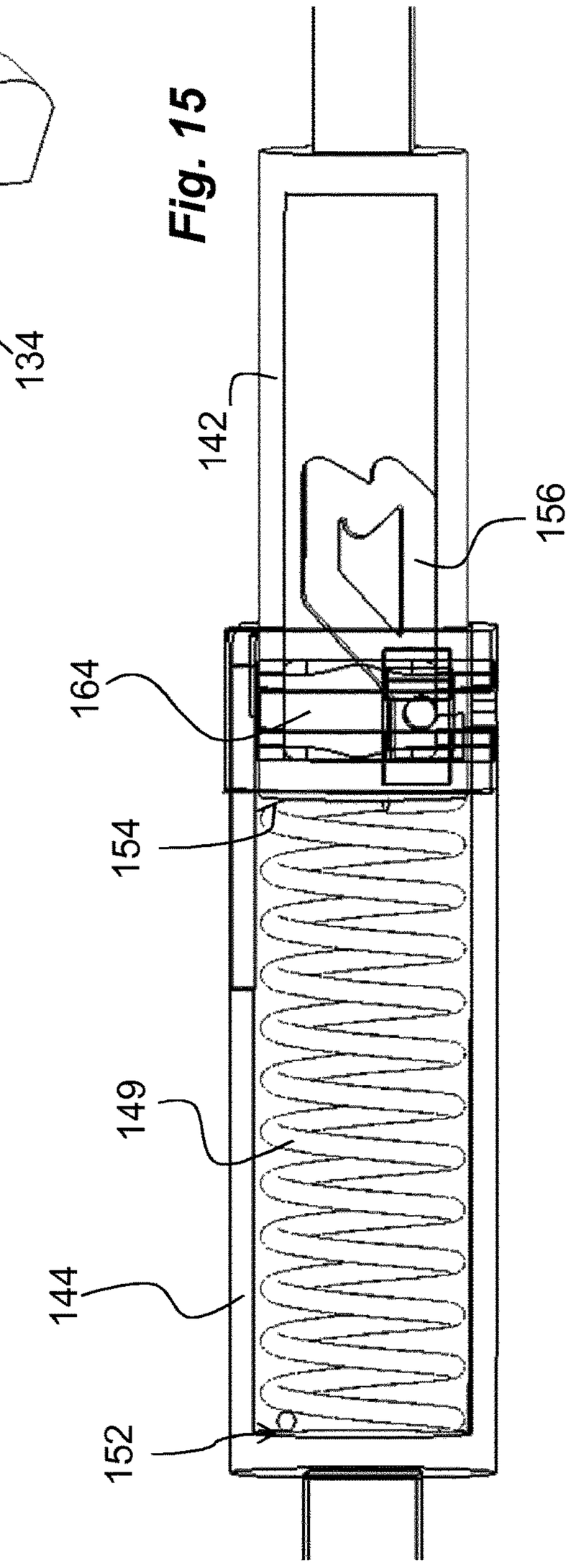
Fig. 15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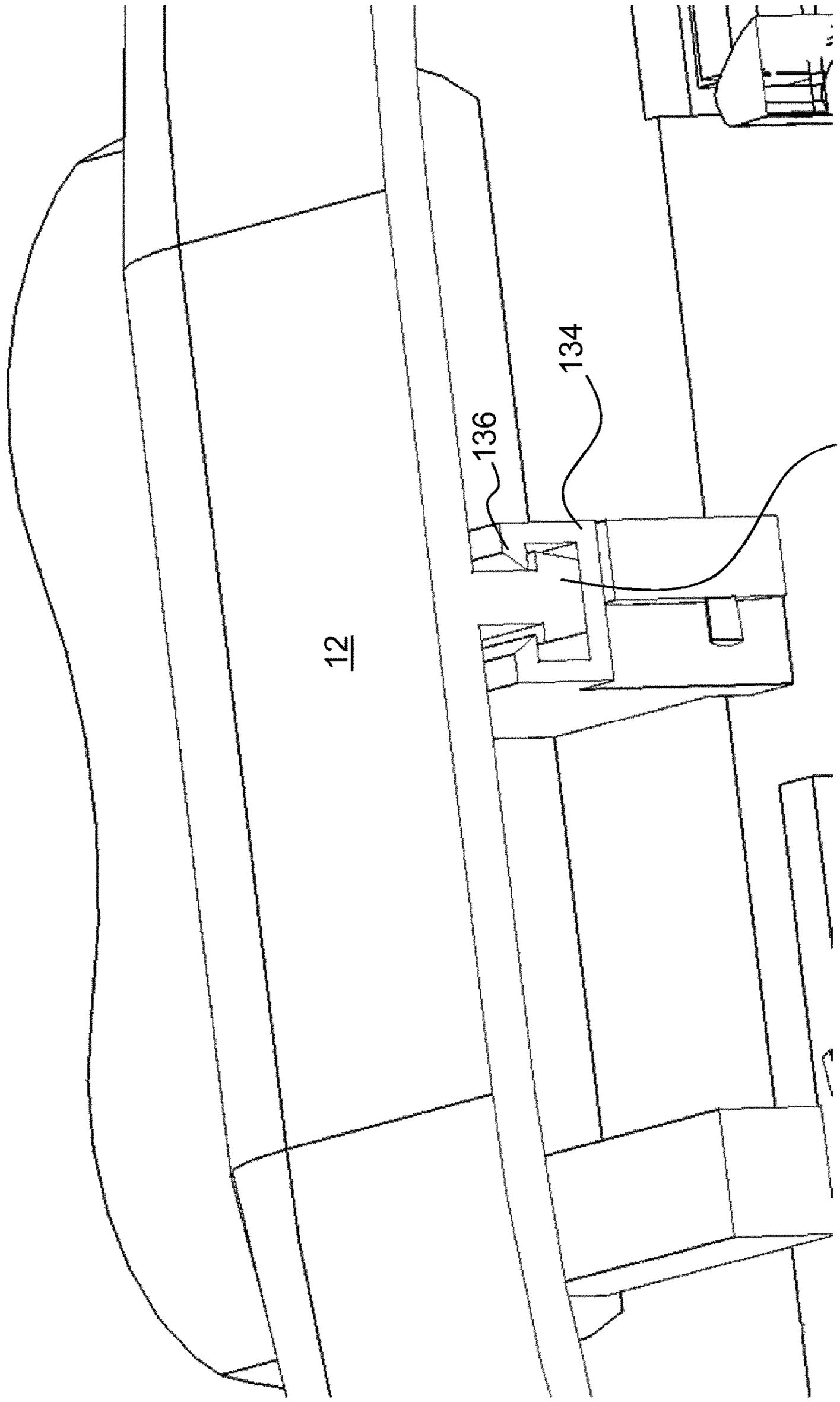

Fig. 14

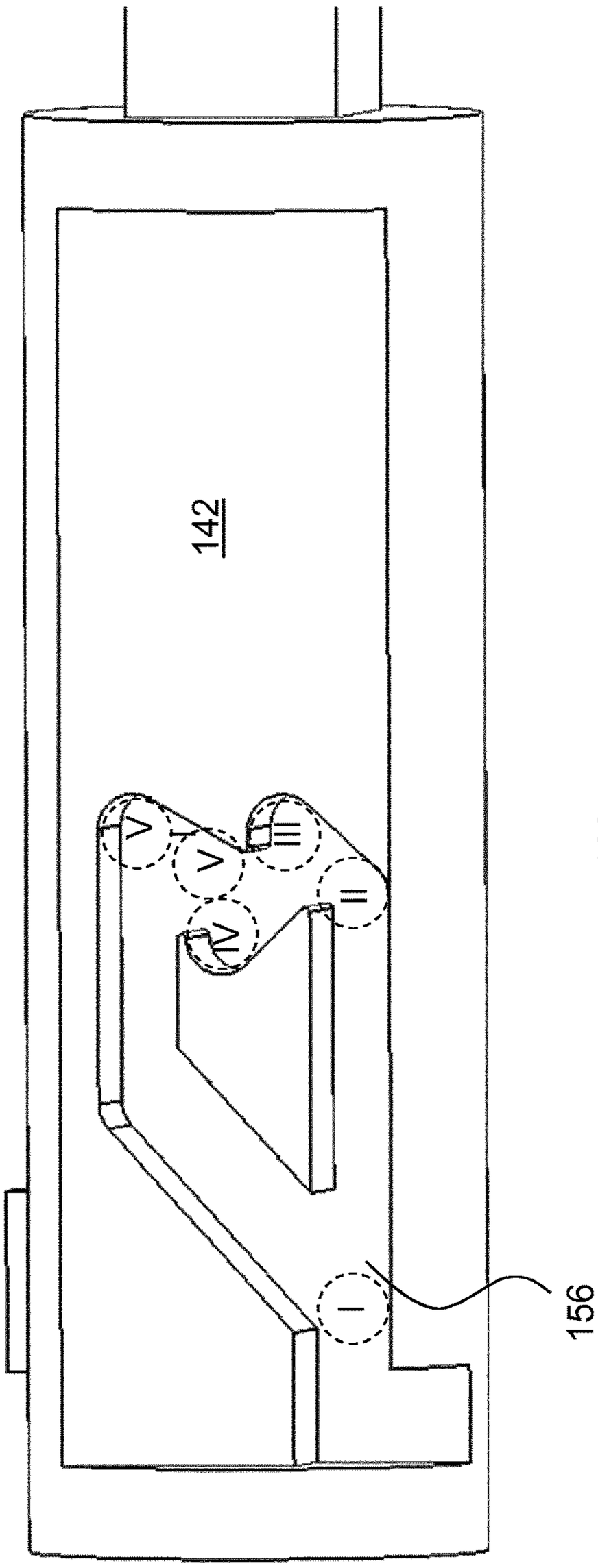

Fig. 16

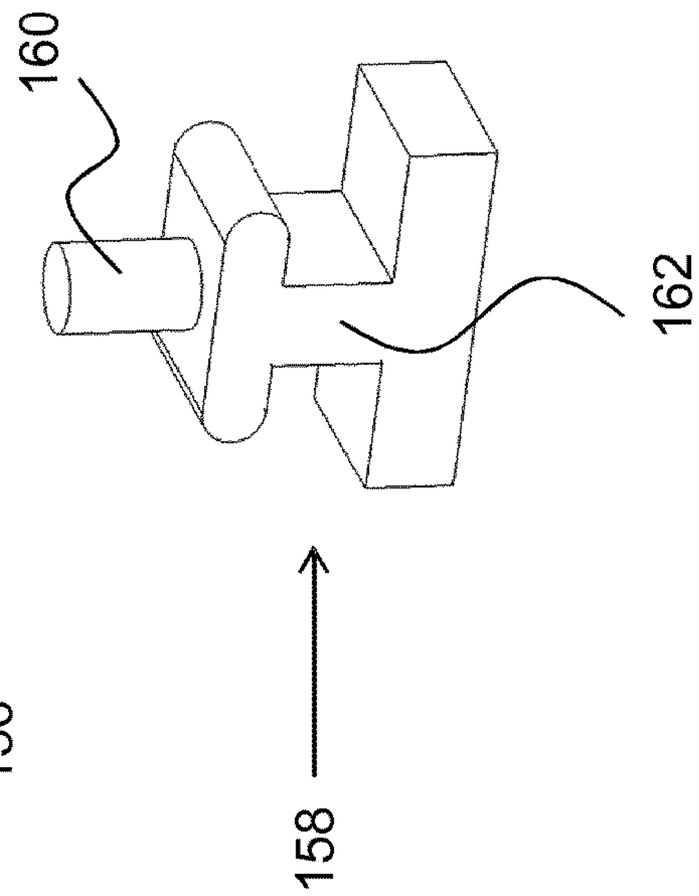

Fig. 17

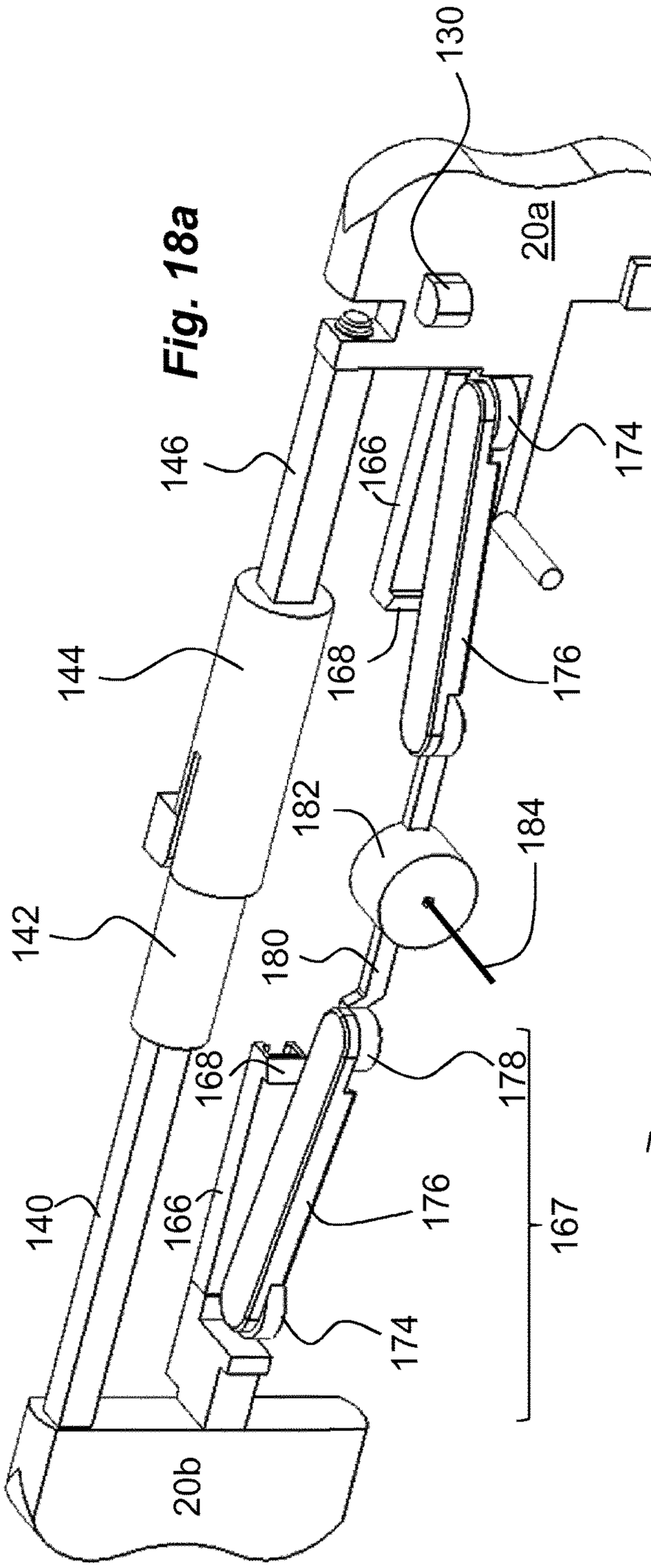

Fig. 18a

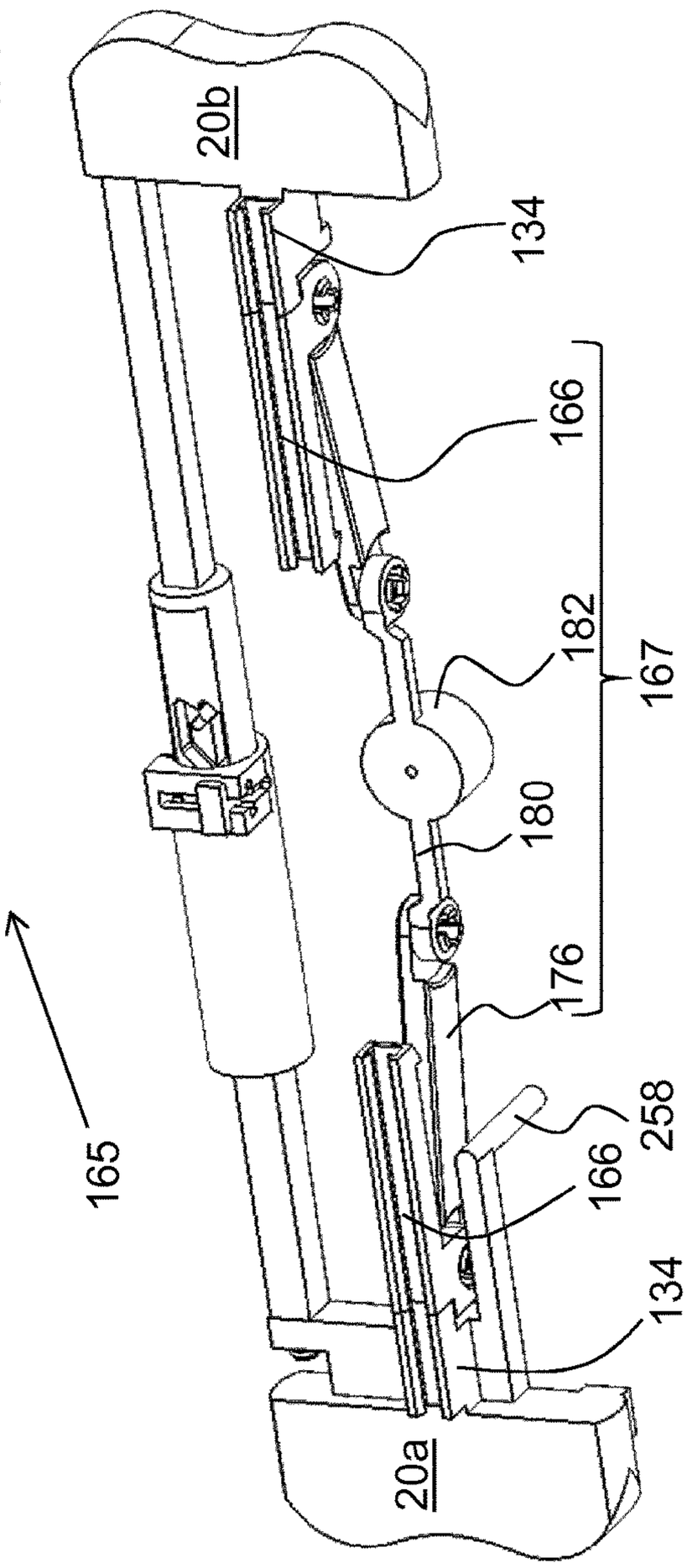

Fig. 18b

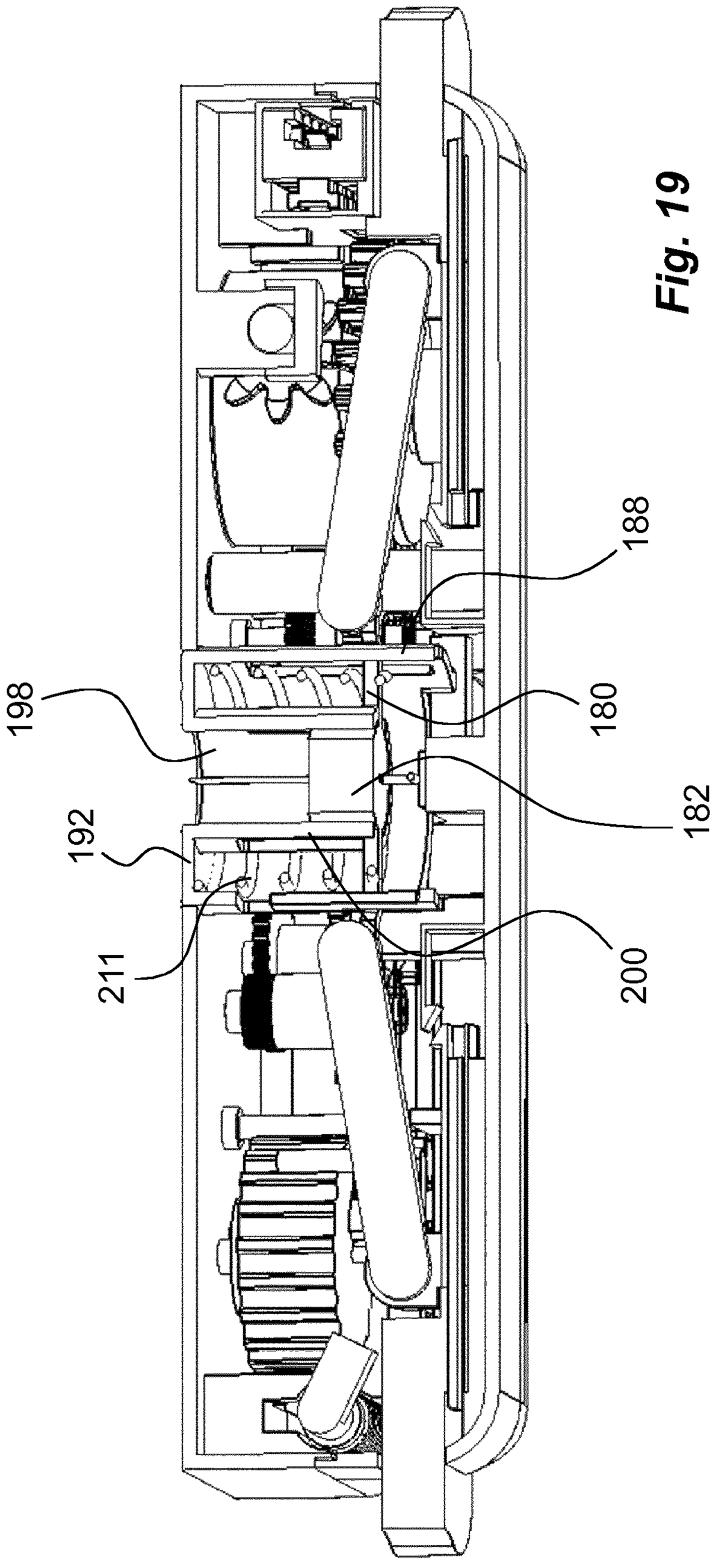

Fig. 19

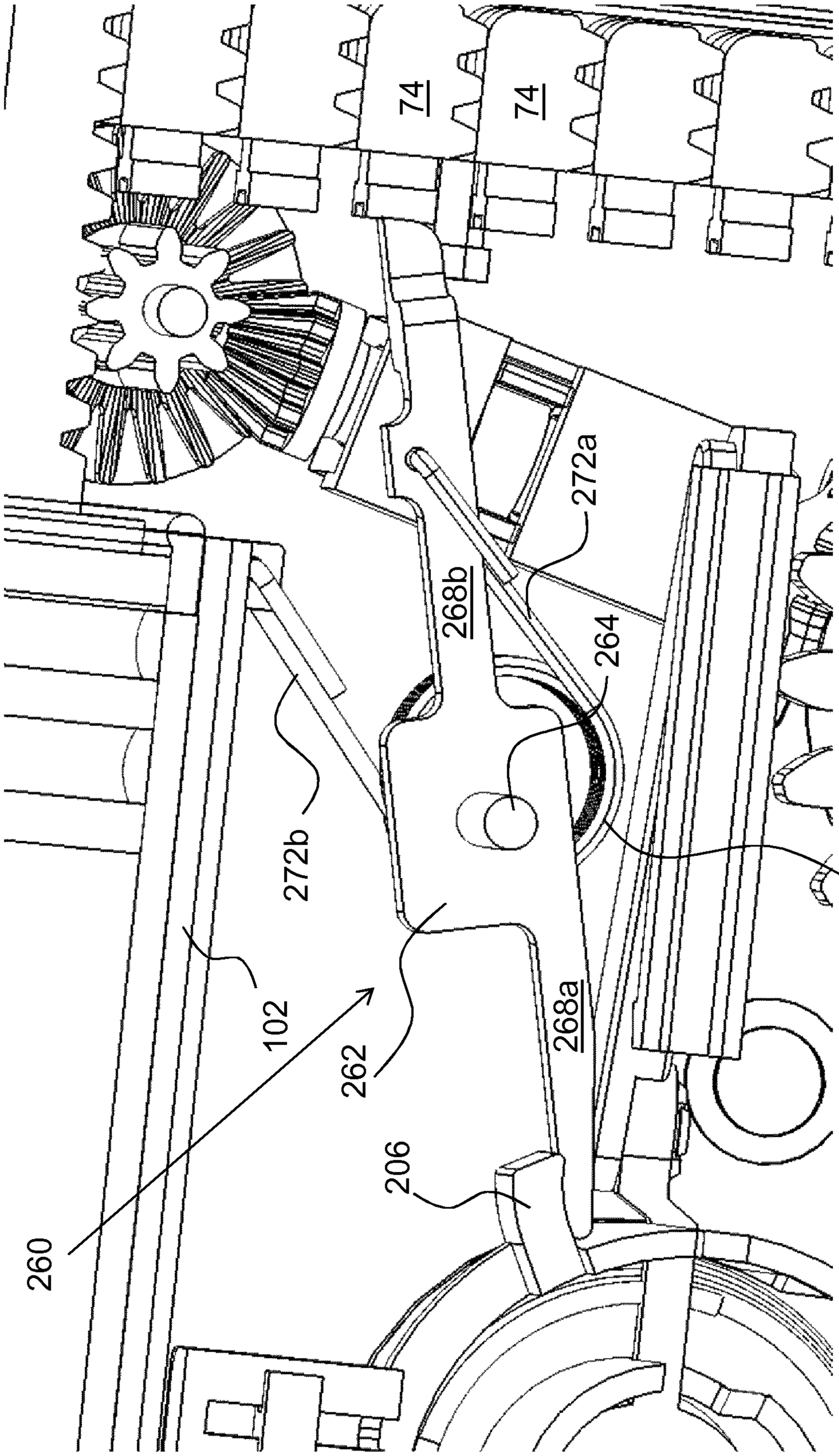

Fig. 20

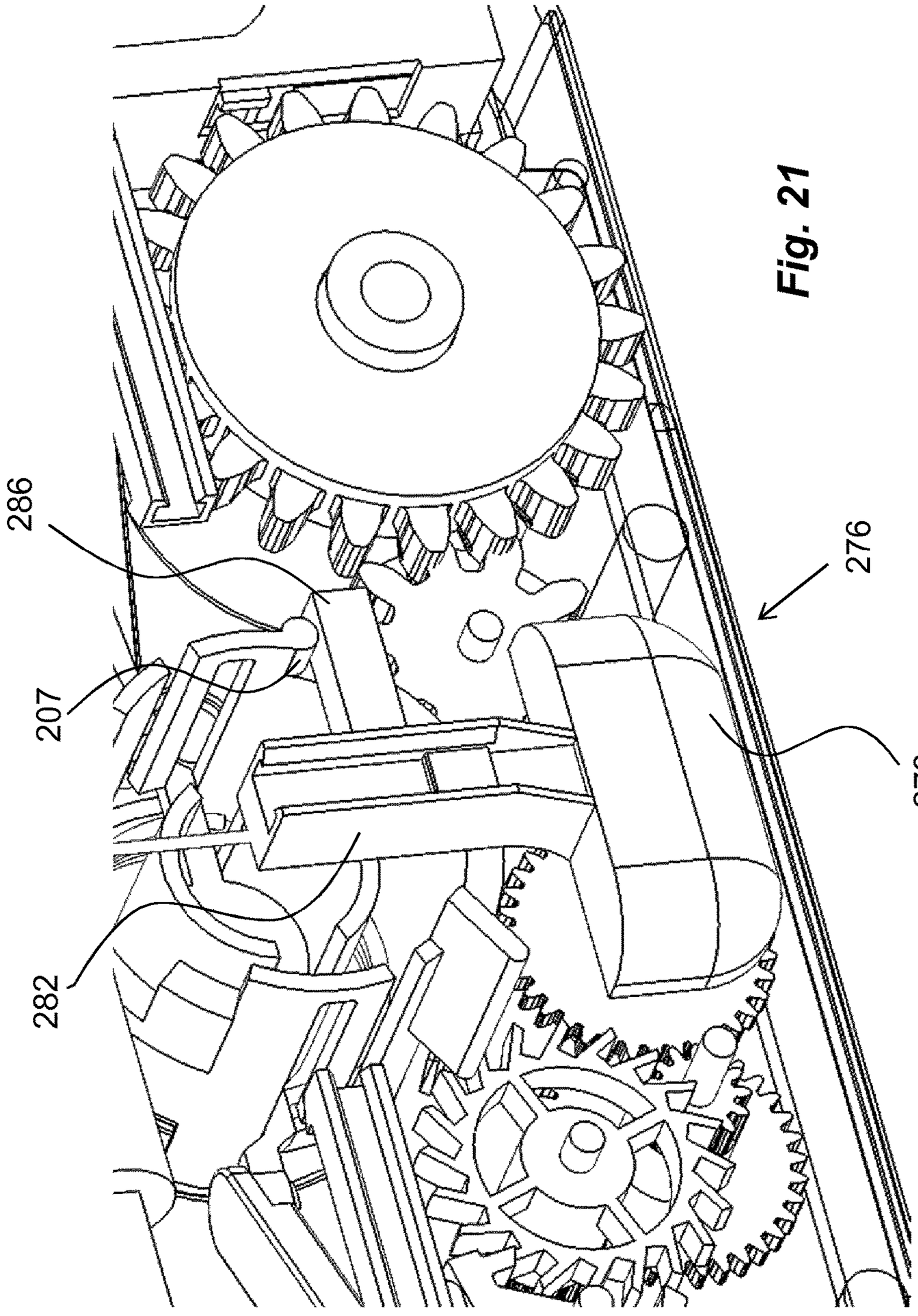

Fig. 21

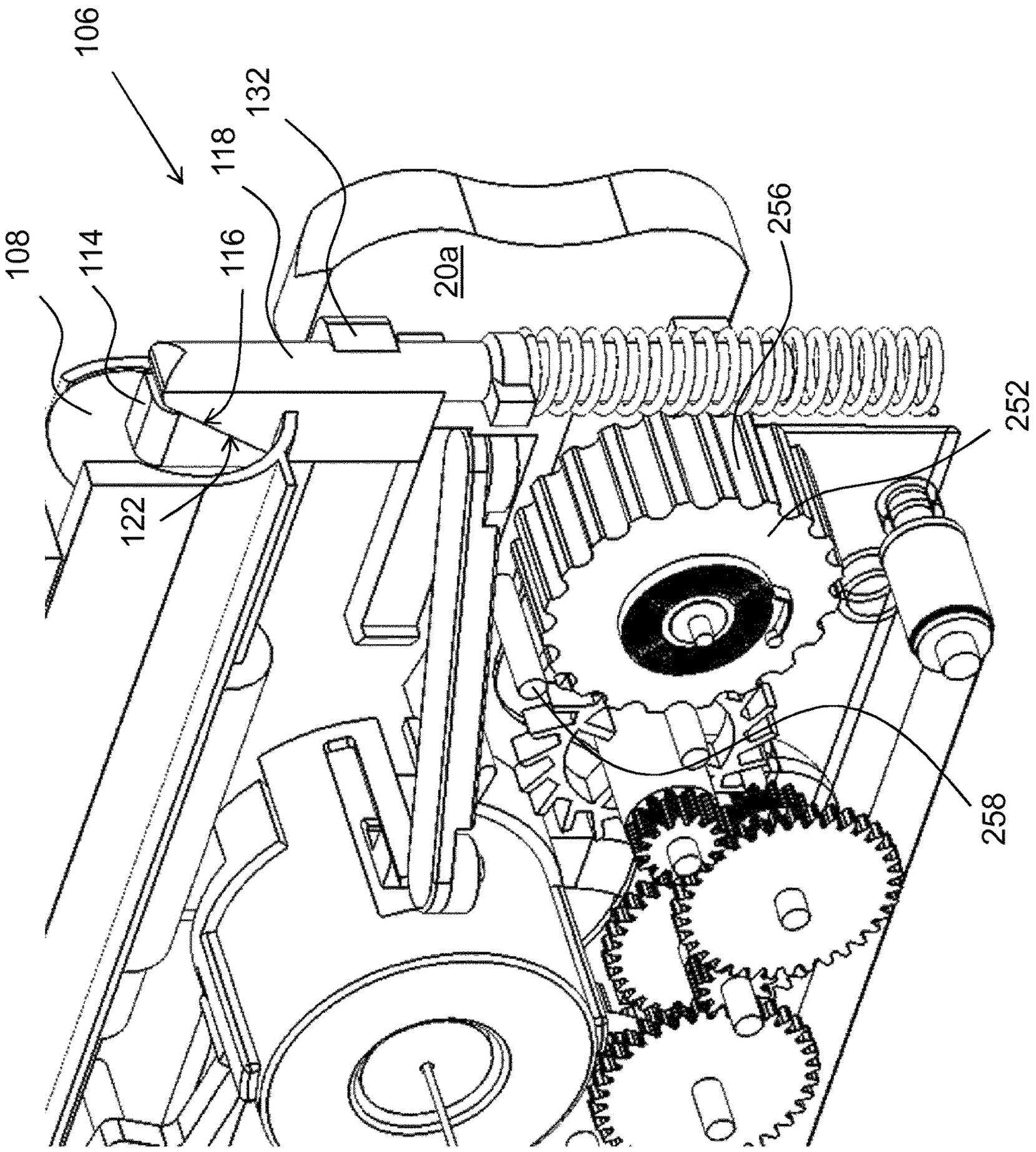

Fig. 22

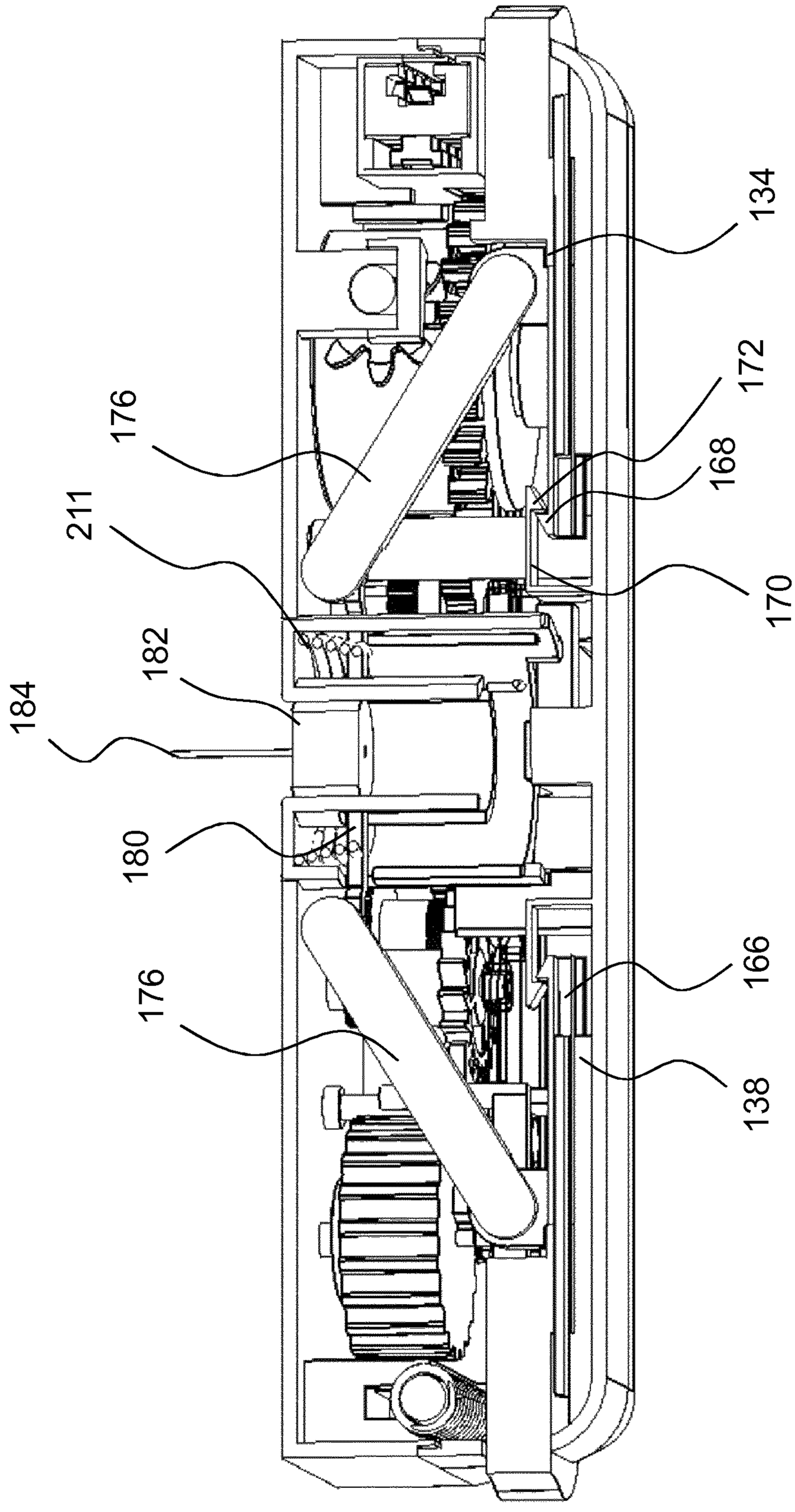

Fig. 23

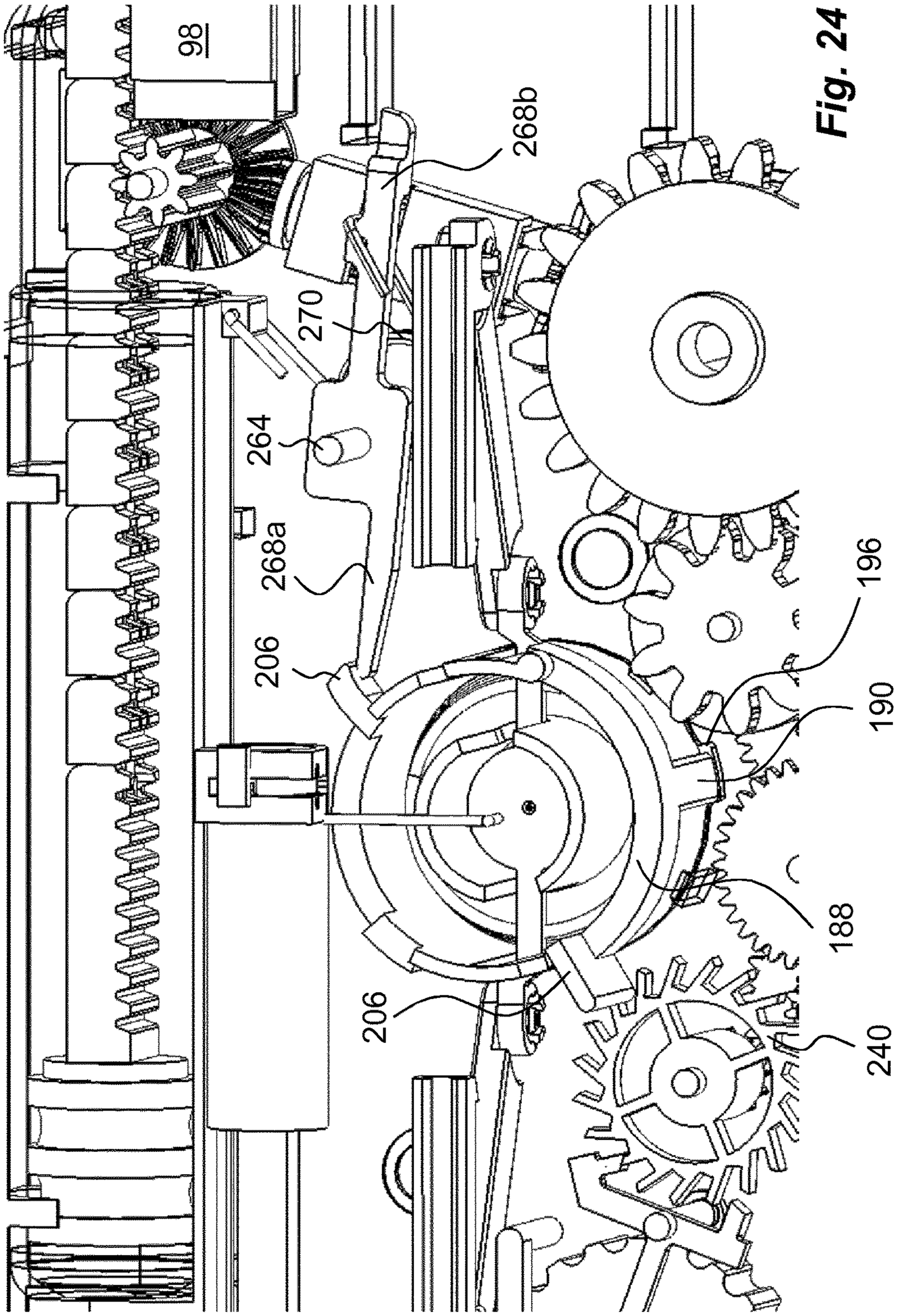

Fig. 24

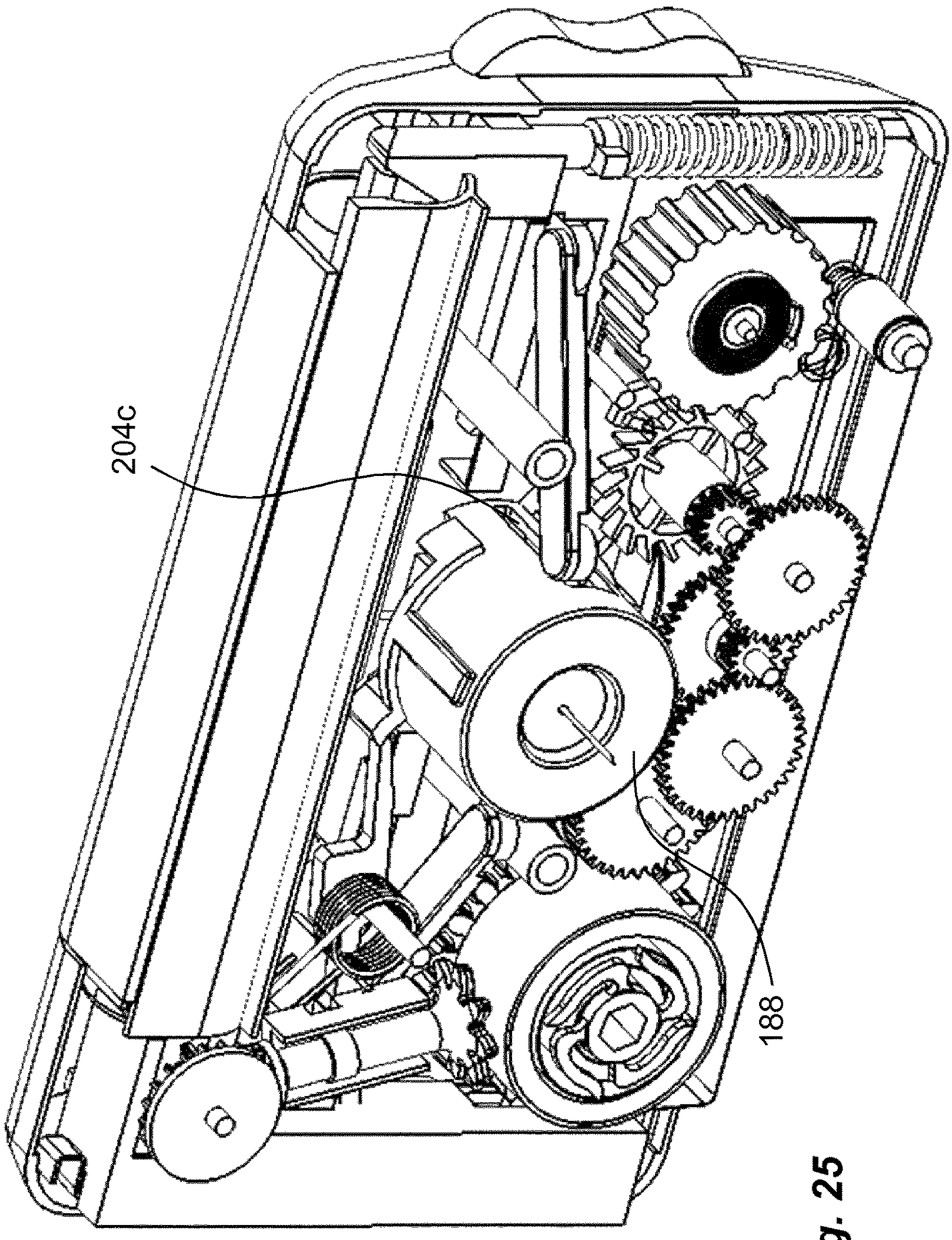

Fig. 25

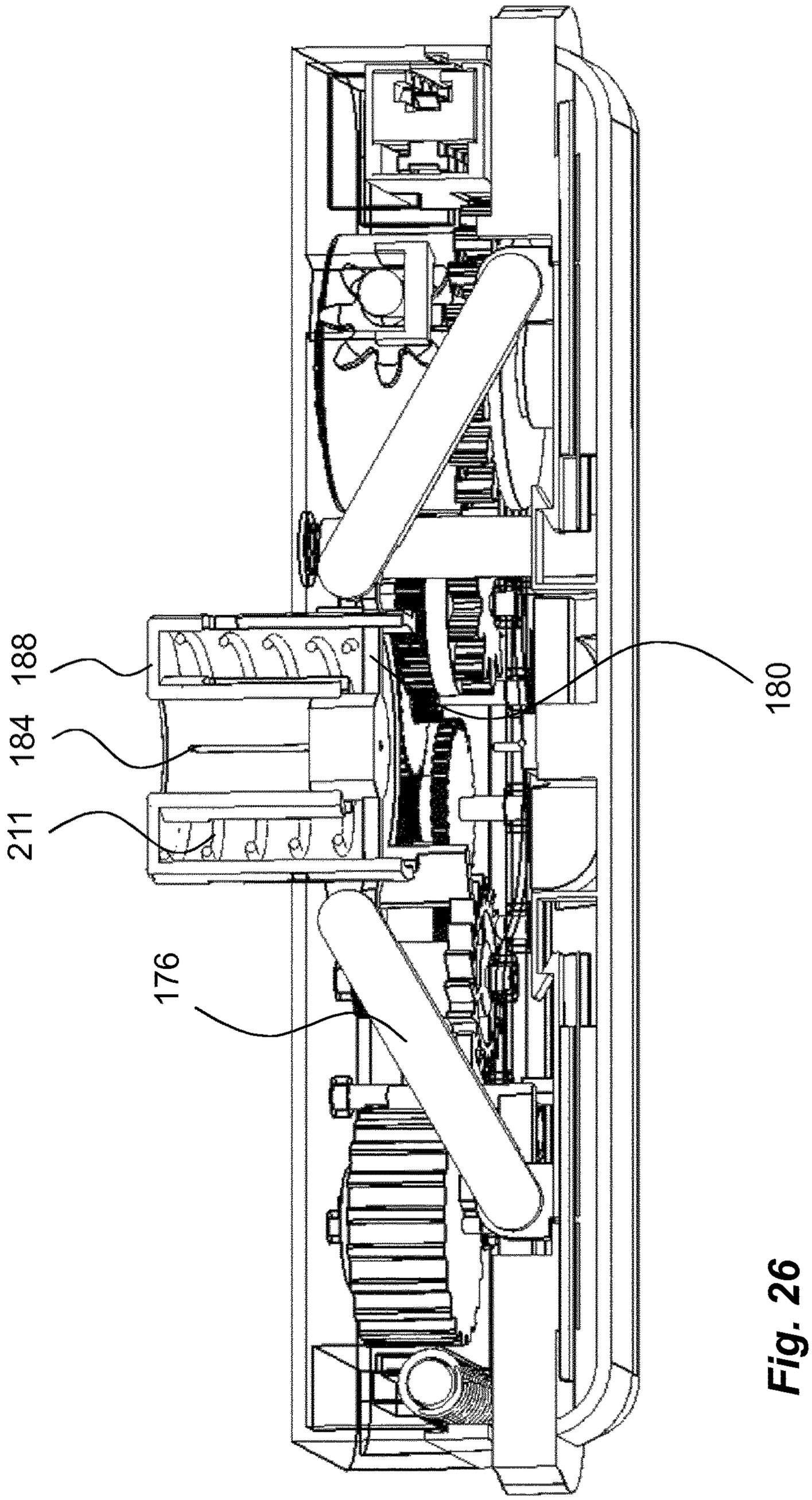

Fig. 26

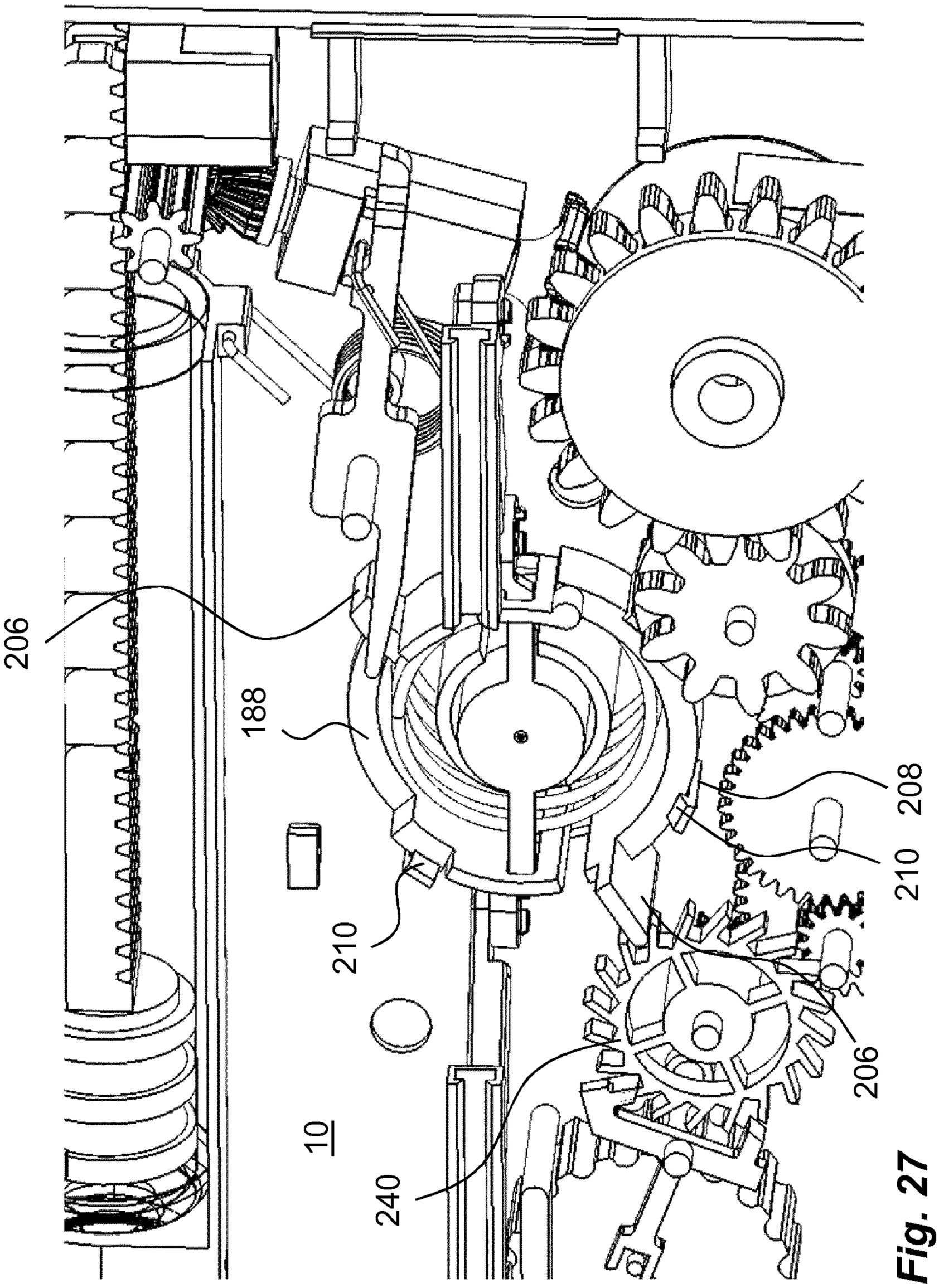

Fig. 27

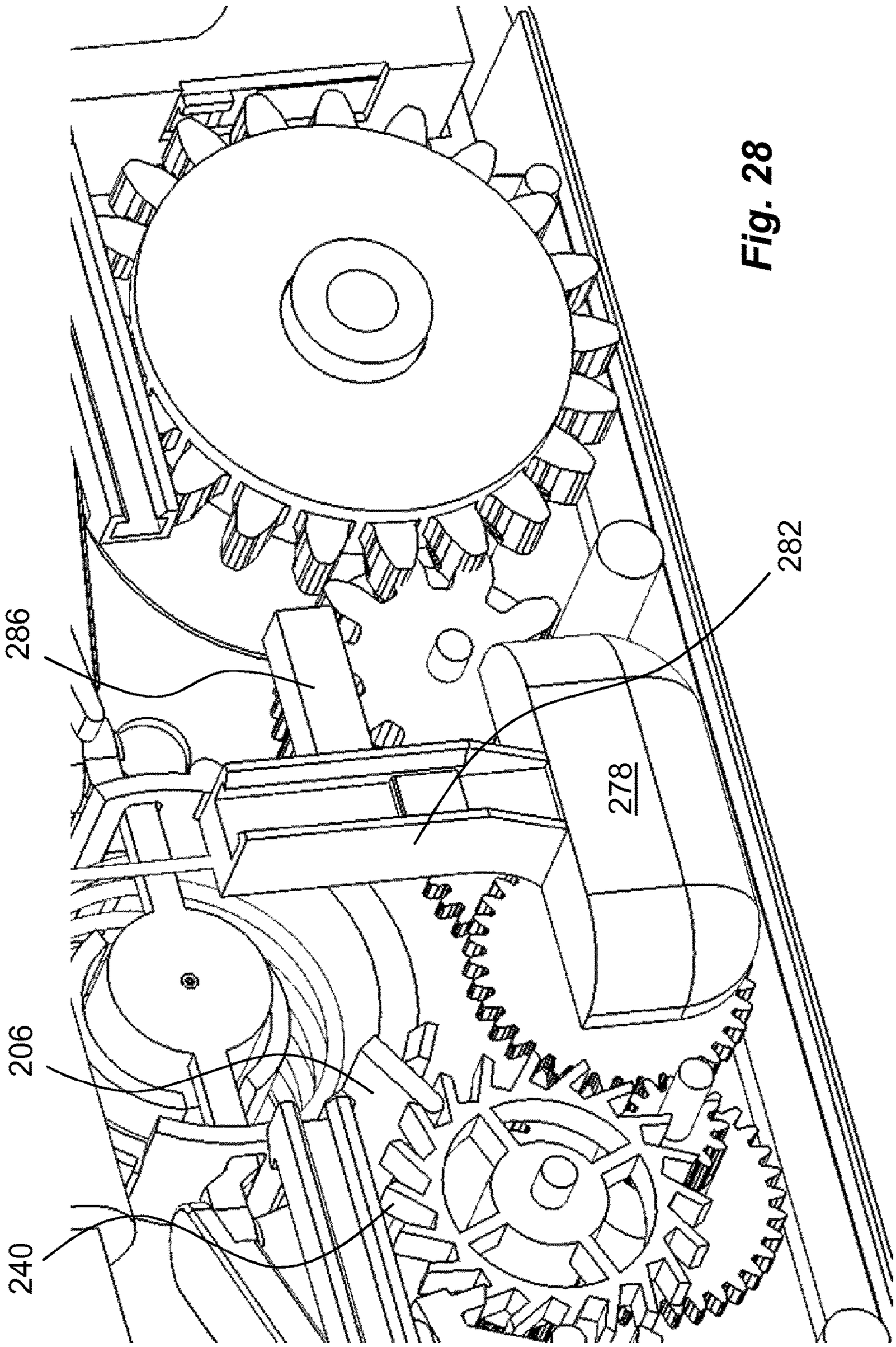

Fig. 28

PORTABLE INFUSION PUMP

TECHNICAL AREA

The present invention relates to a medicament delivery device and in particular a compact and easy to use infuser.

BACKGROUND OF INVENTION

For a number of years infusers have been used that provides the patient or user with the means of administering a drug in an easy way without the need for a medically trained person, such as a physician or nurse to handle the device.

One drawback with these infusers is that they have a medicament container of a certain length as well as a plunger rod acting on said medicament container for delivering a dose of medicament, also having a certain length, whereby the total length of a device has to be at least the length of the medicament container and the plunger rod. If a drive member is used, such as for instance a drive spring, the length of the device is further increased.

One way of handling this is to make at least the plunger rod shorter for not adding so much to the overall length. One solution to this is to have a flexible plunger rod, which is disclosed for example in EP 1 583 573 where the plunger rod may be bent or formed as a circle. Another solution is disclosed in EP 1 276 529 having a bendable plunger rod with a ratchet on a side surface, where the plunger rod is bent around a cogwheel, for driving the plunger rod.

The drawback with these solutions is that the length might not be increased by the whole length of the plunger rod, but at least by some amount because the circle formed by the bent plunger rod also adds to the length. Further, the dimensions of the device in other directions are increased considerably by these solutions, providing a rather bulky device.

The above-mentioned solutions utilize some sort of power spring wound around a shaft or the like positioned in the centre of the circle formed by the curved plunger rod. These power springs often act directly or almost directly on the curved plunger rod, such as with the device of EP 1 276 529 where the power spring acts on the cogwheel.

The drawback with this drive solution is that it complicates the addition of functions such as activation mechanisms, constant injection speed mechanism, automatic stop mechanisms, just to mention a few. This is mainly because the plunger rod surrounds and thereby blocks access to the plunger drive spring without enlarging the device.

Regarding the injection speed control aspect, some solutions have been devised, such as for example in EP 1 326 659 where an electric motor is utilized for driving the flexible plunger rod. Also document WO 2010/112377 discloses a device utilizing electric motors for driving and controlling the movement and speed of the plunger rod.

The drawback with this is that the device has to rely on electric power in order to deliver a dose of medicament. If any batteries used are depleted, the device cannot be used at all, which may be critical for some types of drugs.

Another drawback with many of the mentioned devices is that there is no feature or mechanism for handling the injection needle after completed injection. When the device is withdrawn, the injection needle completely exposed and may cause injuries to persons handling or coming in contact with the device after use.

BRIEF DESCRIPTION OF INVENTION

In the present application, when the term "distal part/end" is used, this refers to the part/end of the device, or the parts/ends of the members thereof, which under use of the device is located the furthest away from the medicament delivery site of the patient. Correspondingly, when the term "proximal part/end" is used, this refers to the part/end of the device, or the parts/ends of the members thereof, which under use of the device is located closest to the medicament delivery site of the patient.

The aim of the present invention is to remedy the drawbacks of the state of the art medicament delivery devices. This aim is obtained with a medicament delivery device according to the features of the independent patent claim. Preferable embodiments of the invention form the subject of the dependent patent claims.

The medicament delivery device preferably comprises a housing having a compartment inside said housing for positioning a medicament container. The medicament container may have a number of designs that are suitable for delivering a dose of medicament when the device is activated. According to one favourable aspect, the medicament container may be arranged with a stopper that is movable by appropriate means. The medicament container may further be arranged with some connection interface to an injection needle, through which a dose of medicament may be delivered. The connection interface may for example be a septum or other type of membrane or wall that may be penetrated or pierced by a connection element, which connection element may be a pointed end of a conduit in flow communication with the injection needle.

The device may further advantageously comprise a manually operated activation mechanism for activating said device in order to deliver a dose of medicament. The activation mechanism may be operably connected to a number of functions and features of the device.

One such feature may be an actuation mechanism arranged to, upon activation of said activation mechanism, extend the injection needle from a first position inside said housing to a second position wherein a penetration of a patient is performed. Thus, when the device is placed on the body of a patient and the activation mechanism is operated, a penetration of the skin of the patient will be performed by the actuation mechanism, rendering the device ready for delivering a dose of medicament.

In order to provide a dose of medicament from the medicament container through the conduit to the injection needle, the device is preferably provided with a plunger rod in said housing and arranged to act on the stopper of the medicament container. In order to do so, the plunger rod may be operably connected to a driver capable of acting on said plunger rod for delivering a dose of medicament. In this aspect, the driver may advantageously comprise some energy accumulating feature, which energy may drive the plunger rod. The energy accumulating feature may comprise a number of different designs such as compression springs, torsion springs, clock springs, gas springs and the like, just to mention a few.

Preferably the device may comprises a needle cover operably arranged in said housing from a first position inside said housing to a second extended position outside said housing for shielding said injection needle when said injection needle is in said second position. With this solution, the injection needle may be protected when the device is removed from the body of the patient, thereby minimizing the risk of unintentional needle sticks.

According to one feasible solution, the actuation mechanism may comprise a locking mechanism capable of locking said injection needle in said second position. This ensures that the penetration depth of the injection needle is main-

tained during the subsequent injection sequence. Thus, it is not required for the user to operate the activation mechanism after the injection needle has reached the second penetration position.

Further, another favourable feature, the needle cover may comprise locking elements operably arranged to lock said needle cover in said second position. This further minimizes the risk of injuries of the injection needle since the needle cover is locked from movement.

According to another favourable feature, the activation mechanism may comprise two operating elements placed on opposite sides of said device. This solution of the activation of the device is advantageous since the operating elements may be operated by one hand of the user gripping the device. According to a further favourable solution, the operating elements may comprise activation buttons, which buttons are manually depressed for activating said device. Since the buttons are placed on opposite sides of the device, the forces for depressing the buttons are directed towards each other. Thus the forces will not affect the position of the device on the body of the patient, which is an advantage during the penetration and the injection sequence, because any movement of the device when the injection needle has penetrated the body will cause pain and discomfort.

According to one feasible solution, the activation buttons may be connected to said injection needle via a linkage comprised in said actuation mechanism, thereby enabling movement of said injection needle to said extended position when said buttons are depressed. The linkage thus enables movement of the injection needle in directions deviating from the movement directions of the activation buttons, for example a direction ninety degrees in relation to the activation buttons. When using a linkage, the locking mechanism of said injection needle may preferably be comprised in the linkage.

In order to ascertain a smooth and more or less constant injection speed, the device may further comprise an injection speed control mechanism operatively connected to said driver. With such a mechanism, the injection speed may be chosen and controlled in a positive manner. This may be an important feature for medicament solutions that for example are painful when delivered in larger quantities quickly. The dose delivery may then be set and controlled to deliver very small quantities continuously for longer time periods.

According to one feasible solution, the injection speed control mechanism may for example comprise a pallet fork acting on an escapement wheel, as well as a transmission between said drive means and said escapement wheel. This solution provides possibilities of a choosing and changing injection speeds in a wide range. The use of a transmission enables the choice of gearing those suites the delivery speed of a certain medicament. In order to provide a certain injection speed, the escapement wheel is preferably drivably connected to a drive spring.

According to another preferable solution, the device may further comprise an auto-stop mechanism capable of permanently stopping said injection speed control mechanism at the end of a dose delivery sequence. Thereby it is clearly indicated to a user that the injection is completed and that the device may be removed from the patient.

To further enhance the usability of the device, it may further comprise a manually operable stop mechanism capable of permanently stopping said injection speed control mechanism upon activation. This may for example be an advantage in a situation when the user for some reason has to remove the device from the body. The stop mechanism will then ascertain that no medicament is expelled from the device after removal.

According to another feasible solution, the device may further comprise a manually operated pausing mechanism capable of temporarily stopping and subsequent starting of the injection speed control mechanism upon activation. This may for example be an advantage when the user has started the injection sequence but wants to pause it for some reason. The injection speed control mechanism is then stopped only temporary and may be resumed by the user. The pausing mechanism may for example by operably connected to the activation mechanism.

According to another feasible solution, the device may also comprise a medicament container penetration mechanism operably connected to said activation mechanism for creating, upon activation, a communication between the medicament inside said medicament container and said injection needle. In this manner, the content of the medicament container is not affected in any way before the device is activated. Thus, the medicament container may be inserted into the device at any time without the risk of degrading the medicament, because a passage between the interior of the medicament container and the injection needle is only obtained after activation of the device.

These and other aspects of, and advantages with, the present invention will become apparent from the following detailed description of the invention and from the accompanying drawings.

BRIEF DESCRIPTION OF DRAWINGS

In the following detailed description of the invention, reference will be made to the accompanying drawings, of which

FIG. **1** is a perspective view of an embodiment of a medicament delivery device,

FIG. **2** is a perspective view of the device of FIG. **1** turned 180 degrees,

FIG. **3** is a perspective view of the device of FIG. **1** with a housing part removed,

FIG. **4** is a perspective view of the device of FIG. **1** turned 180 degrees in relation to FIG. **3** and with a housing part removed,

FIGS. **5-15** are detailed views of components and mechanisms comprised in the device of FIG. **1**,

FIGS. **16-28** show different functional positions of the device during use.

DETAILED DESCRIPTION OF THE INVENTION

The embodiment of a medicament delivery device shown in the drawings comprises a housing, which may be in two housing parts **10**, **12**, FIGS. **1** and **2**. It is of course feasible that it comprises more than two housing parts. Preferably, the complete housing has a generally rectangular shape having a measure or thickness as seen along a proximal-distal axis **14** that is much less than the dimensions in the other two directions, vertical **16** and horizontal **18**. The housing is arranged with operating elements, **20***a, b* in the embodiment shown, FIGS. **1** and **2**, as two buttons arranged on opposite side surfaces of the device.

The device is arranged with a driver **50**, the function of which will be explained below. The driver comprises a shaft **24**, FIG. **5**, which shaft is rotatably arranged inside the housing and journalled with a distal end in a seat **26**, FIG.

6, on the inner surface of the distal housing part **12**. An Allen keyhole **22** is arranged on an end surface of a shaft **24**, where the Allen keyhole **22** is accessible via an opening on the proximally directed housing surface, FIG. **2**. A proximal end of the shaft **24** is arranged with a number of arms **28**, FIG. **5**, that extend in a generally circumferential direction. The free ends of the arms **28** are arranged with radially outwardly directed edges **30**. The proximal end of the shaft **24** with the arms **28** is intended to fit into a seat **32**, FIG. **7**, on the inner surface of the proximal housing part **10**. The seat **32** is surrounded by an annular ledge **34** having radially inwardly directed teeth **36** of a certain configuration. The teeth **36** are intended to cooperate with the free ends of the arms **28** as will be described.

The driver **50** further comprises a flat spiral clock spring **38**, FIG. **5**, wound around the shaft **24**, wherein an inner end of the spiral clock spring **38** is attached to the shaft **24**. The spring **38** is further arranged inside a spring housing **40**, FIG. **5**, designed as a generally tubular part. An outer end of the spiral clock spring **38** is attached to an inner surface of the spring housing **40**. The spring housing **40** is further arranged with a sidewall **42**, FIG. **5**, having a central opening **44**, through which the shaft **24** can extend. On the outer circumferential surface of the spring housing **40** a ratchet **46** is arranged, FIG. **5**. The ratchet **46** is intended to cooperate with a cogwheel **48** of the driver **50**, FIG. **8**. The driver **50** further comprises a shaft **52** where the cogwheel **48** is attached to one end such that the shaft **52** extends generally in the radial direction of the spring housing **40** as seen in FIG. **8** along line **53**. The shaft **52** of the driver **50** is journalled in the proximal housing part **10** by support elements **54**, FIG. **7**. A second cogwheel **56**, FIG. **8***b*, is attached to the second end of the shaft **52**, having a generally conical shape. The second cogwheel **56** is arranged to be in contact with teeth of a third mating cogwheel **58**. The third mating cogwheel **58** is journalled on a shaft **60** having an extension generally perpendicular to the extension of the shaft **52**. Attached to the third mating cogwheel **58**, or made integral with, is a drive wheel **61** having teeth **62** around its circumference. These teeth **62** are arranged to cooperate with corresponding teeth **64** on a plunger rod **66**, FIG. **4**.

In the embodiment shown the plunger rod **66** is of a certain configuration, FIGS. **9** and **10**. The plunger rod **66** generally has a rectangular configuration as seen in a cross-sectional view. Further the plunger rod **66** is divided up into a number of plunger rod segments. The end of the first plunger rod segment **68** that is to be in contact with a stopper **69** of a medicament container **70**, FIG. **4**, is arranged with a generally circular pusher plate **72**, FIG. **9**, having a diameter somewhat less than the inner diameter of the medicament container **70**. The first plunger rod segment **68** has a certain length.

The following plunger rod segments **74**, FIG. **9**, are somewhat shorter. All plunger rod segments **74** are arranged with connection elements that comprise generally vertically arranged cut-outs **76** at their distal ends, FIG. **10**. The sidewalls of the cut-outs **76** are arranged with generally vertically directed grooves **78**, FIG. **10**, having a certain configuration. Further, each plunger rod segment apart from the first segment, is arranged with a proximally directed nose **80** designed to fit into the cut-out **76** of a previous plunger segment **68**. Further the nose **80** is arranged with generally vertically extending ledges **82** having similar configuration as the grooves **78** of the cut-out **76**, whereby the ledges **82** may fit into the grooves **78**. Further, the cut-outs **76** are arranged with flexible tongues **84**, FIG. **10***b* that engage a surface of the nose **80** of a subsequent plunger rod segment so as to lock the segments to each other.

The plunger rod segments **74** are arranged in a generally vertical stack on top of each other and directed such that the nose **80** of the segments point in the same direction, FIGS. **8***a* and **9**. The stack of plunger rod segments is held in place inside the housing by a magazine **86**, FIG. **9** providing side supports on three sides. The fourth side is arranged with an elongated slit **88**, FIG. **9**. In the slit **88** a flat band spring **90** is arranged having a first upper end attached to a fixture post **92** on the proximal housing part **10**, FIGS. **4** and **7**. The second lower end of the band spring **90** is arranged with a coil **94**, FIG. **9**, which coil **94** fits into a cavity **96** attached to a plunger rod follower **98** positioned inside the magazine **86**, FIG. **9**. The function of the described components will be explained below.

The proximal end of the plunger rod **66** extends into a space in the device intended to accommodate the medicament container **70**, FIG. **4**. The space is accessible via a hingedly attached lid **100**, FIGS. **1** and **4**, on an upper area of the housing. Inside the space a holder or cartridge retainer **102**, FIGS. **3** and **4**, is arranged, on which the medicament container **70** may be placed. In that respect, the cartridge retainer is arranged with a holding portion **104**, FIG. **4**, in which a neck portion **105**, FIG. **11**, of the medicament container **70** fits. A penetration mechanism **106** is further arranged in the device. It comprises a cup-shaped element **108**, FIG. **11**, arranged slidable in relation to the holding portion **104** and thus the neck portion **105** of the medicament container as seen in a longitudinal direction thereof. The cup-shaped element **108** is arranged with a hollow needle or a hollow pointed spike **110** directed towards the neck of the medicament container, FIG. **11**, intended for piercing a septum **112** of the neck portion **105** of the medicament container **70**.

Further, an end surface of the cup-shaped element **108** is arranged with a ledge **114** having an inclined surface **116**, FIG. **12**. The ledge **114** is intended to interact with a pusher **118** of the penetration mechanism. The pusher **118** is designed as a generally elongated rod **120** provided with an inclined surface **122**, FIG. **12**, arranged to be in contact with the inclined surface **116** of the cup-shaped element **108**. The pusher **118** is further arranged with a compression spring **124** arranged surrounding the rod **120** and fitted between a generally radially directed ledge **126** of the rod and a seat **128** in the housing parts as seen in FIG. **7**. Further, in an initial position as seen in FIG. **12**, the pusher **118** with its inclined surface **122** is somewhat turned in relation to the inclined surface **116** of the cup-shaped element **108**. In this position, the ledge **126** fits into a recess **127** in the seat **128**, FIG. **7**, thereby locking the pusher with spring **124** compressed. Further, a generally radially extending protrusion **132** is arranged on the rod of the pusher, below a surface area **131** on the side of the pusher **118**, FIG. **12**.

The device is further arranged with an activation mechanism **129**, FIG. **13**. It comprises the two operating elements **20***a* and **20***b* that in the embodiment shown are arranged as push buttons. The push button **20***a* is arranged with a protrusion **130** on its side surface, FIG. **12**. This protrusion **130** is intended to interact with the surface area **131** as will be explained below. Further, the protrusion **130** is positioned such in relation to the protrusion **132** of the pusher that any movement of the pusher in the vertical direction is prevented even if the ledge **126** would unintentionally be moved out of the seat **128**, which might occur if the device was shaken or dropped on a hard surface.

Each push button **20***a, b*, is arranged with a generally U-shaped guide element **134**, FIGS. **4** and **13**, where the free ends of the U's of the guide elements **134** are arranged with inwardly directed ledges **136**, FIG. **14**. These guide elements **134** are intended to interact with guide rails **138**, FIG. **6**, on an inner surface of the distal housing part **12**. The guide rails **138** are arranged with a generally T-shaped cross section as seen in FIG. **14**.

Further, one of the push buttons **20***b* is arranged with an elongated rod **140**, FIG. **13**. The end of the elongated rod **140** is arranged with a generally cylindrical body **142**. The cylindrical body **142** is designed to fit into a tubular body **144**, which also is attached to an elongated rod **146**. The elongated rod **146** is journalled in a post **147** of the other push button **20***a*, FIG. **13**, so as to allow rotational movement of the elongated rod **146** and the tubular body **144** in relation to the push button **20***a*.

The cylindrical body **142** is further arranged with a ridge **148** extending in the longitudinal direction of the cylindrical body **142**. The ridge **148** fits into a slit **150** in the tubular body **144**, such that the bodies **142**, **144** are rotationally locked to each other while allowing longitudinal movement between them. A compression spring **149**, FIGS. **13** and **15**, is arranged inside the tubular body **144** acting between an end wall **152** of the tubular body **144** and an end wall **154** of the cylindrical body **142**. The cylindrical body is further arranged with grooves **156**, FIGS. **15** and **16**, having a certain configuration as will be described. A guide element **158**, FIGS. **13** and **17**, is arranged to be placed in the grooves with a pin **160**. The pin **160** is attached to a generally T-shaped body **162**, which body **162** fits into a slit **164** in the tubular body, which slit **164** is arranged generally perpendicular to the longitudinal direction of the tubular body **144**, as seen in FIG. **13**. These components form a pausing mechanism, as will be described.

An actuation mechanism **165**, FIG. **18**, is further arranged to the activation mechanism. The actuation mechanism **165** comprises two elongated guide rods **166**, FIG. **18**, arranged slidable on the guide rails **138**, FIG. **6**. In that respect, the guide rods **166** preferably have the same shape as the guide elements **134** when seen in a cross-section. Each guide rod **166** is arranged with a ledge **168**, FIG. **18***a*, extending generally transversal to the longitudinal direction of the guide rod **166**. Each ledge **168** is designed to cooperate with a generally L-shaped holding element **170**, FIG. **6**, where the free end is arranged with a ledge **172** arranged to grip the transversal ledge **168** of the guide rod **166** as will be described.

A linkage **167** is comprised in the actuation mechanism, FIG. **18**, wherein each guide rod **166** is further arranged with a first attachment post **174** comprising a bearing passage. A bearing shaft of an actuator arm **176** is journalled in the first attachment post **174**. The opposite end of the actuator arm **176** is provided with a bearing shaft intended to fit into a bearing passage of a second attachment post **178**. The second attachment post **178** is in turn attached to an arm **180** of a needle holder **182**. The needle holder **182** is designed with a generally cylindrical outer shape. The needle holder is arranged with a central passage through which an injection needle **184** is extending. Further, a tube **186** is attached to one end of the injection needle **184**, FIG. **11**. The tube **186** then connects to the spike **110**, thereby providing a passage between the spike **110** and the injection needle **184**.

A needle cover **188** is further arranged to the device, FIGS. **3** and **7**. It comprises a generally tubular body having a number of longitudinally extending ribs **190** on its outer surface, FIG. **7**, in the embodiment shown two ribs **190** arranged on opposite sides of the needle cover **188**. The ribs **190** end a short distance from a proximal end wall **192**, FIG. **3**, of the needle cover **188**, which distance generally corresponds to the thickness of the proximal housing part **10**. This is due to that the proximal end of the needle cover protrudes through a passage **194** in the proximal housing part, FIG. **7**, where proximal end surfaces of the ribs **190** abut the inner surface of the proximal housing part **10** adjacent the passage **194**.

The passage **194** is further arranged with cut-outs **196**, FIG. **7**, having generally the same shape as the ribs **190** in a cross-sectional view. The proximal end wall **192** of the needle cover **188** is further arranged with a central passage **198**, FIGS. **3** and **19**, which central passage **198** is surrounded by a generally tubular element **200**, FIGS. **7** and **19**, extending in the distal direction. The tubular element **200** has a diameter somewhat larger than the outer diameter of the needle holder **182**, where the latter is able to slide inside the tubular part along the proximal-distal axis **14**. The tubular element **200** is further arranged with two slits **202**, FIG. **7**, in which the arms **180** of the needle holder **182** may be positioned.

Further the needle cover **188** is also arranged with slits **204**, with a first part **204***a* open in the distal direction, where the first part **204***a* transforms into a second generally circumferential second part **204***b*, which in turn transforms into a third part **204***c* generally parallel with the first part **204***a* but closed in the distal end. The needle cover **188** is further arranged with radially outwardly extending ledges **206**, FIG. **7**, one on each side of the needle cover **188** as seen in the transversal direction. Further, a longitudinally extending ledge **207**, FIG. **7** is provided in the distal end surface of the needle cover **188**. Arms **208** are further arranged on the inner surface of the proximal housing part surrounding the passage extending in the distal direction, FIG. **7**. These arms are arranged with radially inwardly extending ledges **210**. Further, a needle cover spring **211**, FIG. **19**, is arranged between the inner surface of the end wall **192** of the needle cover **188** and the arms **180** of the needle holder **182**. Also, a needle cap **209**, FIG. **2**, is releasably arranged in the central passage **198** of the needle cover **188**, surrounding the needle and keeping it sterile.

The device is further arranged with an injection speed control mechanism **212**, FIG. **8**, that preferably is capable of providing a constant injection speed during the injection. It comprises a transmission **213**, FIGS. **8***a* and **8***b*, with a first cogwheel **214**, FIG. **8***b*, acting on the ratchet **46** on the outer surface of the spring housing **40**, where the first cogwheel **214** has a smaller diameter than the ratchet **46**. The first cogwheel **214** is attached to a second cogwheel **216** having a diameter generally corresponding to the first cogwheel but with a larger number of teeth, wherein the first and second cogwheels **214**, **216** are rotatably arranged to a first shaft **218**. The second cogwheel **216** is in engagement with a third cogwheel **220** having a smaller diameter. The third cogwheel **220** is attached to a fourth cogwheel **222** having a larger diameter. The third and the fourth cogwheel **220**, **222** are rotatably arranged to a second shaft **224**.

The fourth cogwheel **222** is then in engagement with a fifth cogwheel **226** having a smaller diameter. The fifth cogwheel **226** is attached to a sixth cogwheel **228** having a larger diameter. The fifth and the sixth cogwheels **226**, **228** are rotatably arranged to a third shaft **230**. The sixth cogwheel **228** is in engagement with a seventh cogwheel **232**. The seventh cogwheel **232** is attached to an eighth cogwheel **234**. The seventh and eighth cogwheels **232**, **234** are arranged on a fourth shaft **236**. The eighth cogwheel **234** is

in engagement with a ninth cogwheel **238**. The ninth cogwheel is attached to an escapement wheel **240** having a number of teeth. The ninth cogwheel **238** and the escapement wheel **240** are arranged on a fifth shaft **241**.

A pallet fork **242** is arranged rotatable on a shaft **244** where the arms of the fork are arranged to act on the teeth of the escapement wheel **240**. Further an arm **246** is arranged to the pallet fork **242** where the free end of the arm **246** is arranged with two fingers **248**. These fingers are in engagement with a protrusion **250** attached on a side surface of a regulator wheel **252**. One end of a balance spring **254** is attached to the regulator wheel **252** and the other end of the balance spring **254** is attached to a housing part of the device, capable of oscillating said regulator wheel when activated.

The outer circumferential surface of the regulator wheel **252** is arranged with indentations **256**. The protrusion **250** of the regulator wheel **252** is positioned such in relation to the fingers **248** that oscillation of the regulator wheel **252** will cause the pallet fork **242** to swing back and forth. A more detailed function will follow below. A locking element **258** in the form of an arm attached to the push button **20***a*, FIGS. **3** and **13**, is arranged to fit into the indentations **256** in an initial position of the push button **20***a*, as will be explained below.

The device is further arranged with an auto-stop mechanism **260**, FIG. **20**. It comprises a beam **262** arranged with a shaft **264** journalled in a post **266** on an inner surface of the proximal housing part **10**, FIG. **7**. The shaft **264** is positioned generally midway along the longitudinal direction of the beam, producing two oppositely directed first and second arms **268***a*, **268***b*. An end of the first arm **268***a* is arranged to be in contact with one of the ledges **206** on the needle cover **188**, as seen in FIG. **20**. A torsion spring **270** is further wound around the post **266** and is attached with one free end **272***a* to the second arm **268***b* of the beam. The other free end **272***b* of the torsion spring **270** is attached to a fixed housing part, in the embodiment shown the cartridge retainer **102**. The second arm **268***b* extends through an opening **274** in the magazine **86**, FIG. **4**, having a free end that is in contact with and pushes against the plunger rod segments **74** due to the force of the torsion spring **270**, as seen in FIG. **20**.

The device is further arranged with a manually operated stop mechanism **276**, FIG. **21**. It comprises an actuator element **278** in the form of a button that is accessible via an opening **280** in the distal housing part, FIG. **6**. The actuator element **278** is arranged with an arm **282** having a generally U-shaped form as seen in cross-section. The free ends of the U are arranged with inwardly directed ledges. A guide post **284**, FIG. **6**, attached to the inner surface of the distal housing part, is arranged to fit inside the U-shaped arm, providing guiding action of the stop mechanism when moved linearly as will be described. The stop mechanism **276** further comprises a beam **286** FIG. **21**, directed generally transversal to the arm **282**. In an initial position of the stop mechanism, an upper surface of the arm **282** is in contact with the ledge **207** of the needle cover **188** as seen in FIG. **21**.

Intended Function of the Device

The device is usually delivered without a medicament container. Thus, before use, a medicament container **70** has to be inserted into the device. The lid **100** at the upper end of the device is then opened, whereby the space and the cartridge retainer **102** are accessible. The medicament container **70** is then inserted with a neck portion towards the holding portion **104** of the cartridge retainer **102**. The lid is then closed.

The device is now made ready. This may be done by inserting an Allen key into the hole **22** on the proximal surface of the device and turning the shaft **24** in the clockwise direction. This in turn causes the arms **28** to slide over the teeth **36** because of the direction of the arms in relation to the teeth. Because the inner end of the spiral clock spring **38** is attached to the turning shaft **24** the spiral clock spring **38** is tensioned. When the user stops turning the shaft **24**, it is locked against rotating back because of the edges **30** of the arms **28** now locking against the teeth **36**. Also, after activation of the device, the shaft **24** cannot be rotated again. The device is now ready for delivering a dose of medicament.

In the initial position, the operating elements, the activation buttons **20***a*, **20***b*, are in their extended position as seen in FIGS. **3** and **4**. In this position, the locking element **258** is in engagement with the regulator wheel **252**, as seen in FIG. **3**, whereby action of the constant speed control mechanism **144** is prevented. The balance spring **254** has been tensioned beforehand. The process up to this point may be done without the device being in contact with the patient. In order to be able to deliver a dose of medicament to the patient, the needle cap **209** is removed from the central passage **198** of the needle cover **188** and the proximal surface of the device has to be in contact with some part of the body of the patient, i.e. to releasably attach the device to the body. This may be performed in many ways, by straps, by merely pressing it manually, but preferably the proximal surface is arranged with some sort of adhesive, like sticky tape, with which the device may be fastened to the body. One variant is to have double-sided sticky tape on the proximal surface with an outer protective layer that is peeled off before attachment.

Activation of the Device

When the device is to be activated, the user presses both activation buttons **20***a*, **20***b* towards each other. This causes several things to be initiated.

1. Connection of Medicament Container

When the activation button **20***a* is moved inwards, the protrusion **130** on the activation button is moved along the surface area **131** of the pusher, thereby turning the latter around its longitudinal axis. This causes the ledge **126** to be moved out of the locking engagement with the recess **127** out of contact with the protrusion **132** of the penetration mechanism. Also the protrusion **130** is moved away from the protrusions **132** of the pusher. Thus, the pusher **118** is released and is forced upwards due to the compression spring **124**, FIG. **22**. This causes the inclined surface **122** of the pusher **118** to be moved in contact with the inclined surface **116** of the ledge **114** of the cup-shaped element **108** such that cup-shaped element **108** and the spike **110** is moved towards the neck of the medicament container, which in turn causes the end of the spike **110** to penetrate the septum **112**, creating a passage between the interior of the medicament container and the injection needle via the tube **186**.

2. Penetration of Patient

The inwards pressing of the activation buttons causes the guide elements **134** to move inwards along the guide rails **138**. The guide elements **134** will thereby also move the guide rods **166** inwards, FIG. **23**. Due to the attachment of the needle holder **182** with the guide rods **166** via the actuator arms **176**, the needle holder **182** with its injection needle **184** will move in the proximal direction whereby the

injection needle **184** will extend in the proximal direction beyond the surface of the proximal housing part, causing a penetration of the patient. The advancement of the needle holder **182** with its arms **180** will compress the needle cover spring **211**, as seen in FIG. **23**. When the guide rods **166** have advanced inwards a certain distance inwards, the ledges **168** of the guide rods **166** will pass the ledges **172** of the holding elements **170**. This prevents the guide rods **166** from moving back outwards, and holds thus the needle holder with the injection needle in the extended position as seen in FIG. **23**.

Also, when the activation buttons are pressed inwards, the cylindrical body **142** will move inside the tubular body **144**, compressing the spring **149**. The pin **160** of the guide element **158** will move in the grooves **156** on the outer surface of the cylindrical body as seen in FIG. **16** from a start position I. When the pin **160** reaches position II and follows the inclined surface of the groove to position III, the body **162** of the guide element will move in the slit **164**. In this position, the activation buttons are in their most depressed position and the injection needle has penetrated the patient, who may now release the buttons. This will cause the pin **160** to move to position IV, keeping the activation buttons in a rather depressed state.

3. Start of Injection

The inwards pressing of the activation buttons will also cause the injection to start in that the locking element **258** of the activation button **20***a* is moved out of contact with the indentations **256** of the regulator wheel **252**, as seen in FIG. **22**. The tensioned balance spring **254** will now oscillate the regulator wheel **252**, whereby the pallet fork **242** will start to oscillate back and forth due to the contact with the protrusions **250** on the regulator wheel.

This in turn will cause the escapement wheel **240** to move an increment or rotational angle per time unit, thus controlling the speed. This rotational speed is then transferred through the transmission **213** to the spring housing **40**, determining the rotational speed of the spring housing **40**. However, it is the spiral clock spring **40** that causes the spring housing **40** of the driver **50** to rotate, the transmission merely regulates the rotational speed.

Injection Operation

The rotation of the spring housing **40** will cause its ratchet **46** to move around the circumference, thereby acting on the cogwheel **48** of the driver **50**. Thus the shaft **52** will rotate as will the second conical cogwheel **56**. The rotation of the conical cogwheel **56** is transferred to the third mating cogwheel and thus the drive wheel **61**. Because the teeth **62** of the drive wheel **61** are in engagement with the teeth **64** of the first plunger rod segment **68**, the first plunger rod segment **68** is moved in the direction of the medicament container **70**, whereby the pusher plate **72** acts on the stopper **69** in the medicament container **70**. When the first plunger rod segment **68** has moved a distance towards and inside the medicament container **70**, the space behind the first plunger rod segment **68** is so large that a subsequent plunger rod segment **74** may be pushed in the vertical direction by the flat band spring **90** acting on the lowermost positioned plunger rod follower **98** in the magazine **86**. When the following plunger rod segments **74** are pushed upwards in the vertical direction, they are connected to a previous plunger rod segment in that the ledges **82** of the nose **80** of the subsequent segment fit into the grooves **78** of the cut-out **76** of the previous segment and in that the plunger rod segments are inter-locked by the flexible tongues **84**. In this manner a sequentially "building" of a continuous plunger rod **66** is performed with the segments while performing injection of medicament from the medicament container **70** through the injection needle **184** via the tube **186**.

Pausing of the Injection

The user may pause the injection by pressing shortly at both activation buttons **20**. This will cause the pin **160** of the pausing mechanism to be moved from position IV in FIG. **16** to position V and along the inclined surface to position VI, causing the body **162** to move further upwards in the slit **164**. When the user releases the activation buttons, the spring **149** between the cylindrical body **142** and the tubular body **144** will force the buttons outwardly to the initial start position while the pin **160** also is moved back to the start position I along the walls of the groove as seen in FIG. **16**. The return of the activation buttons to their initial positions will in turn bring the locking element **258** in engagement with the indentations **256** of the regulator wheel **252** such that the rotation of the regulator wheel **252** is stopped. This in turn stops the spring housing **40** from rotation via the transmission, whereby the injection is stopped.

The user may then resume the injection by pressing again on the activation buttons **20***a, b*, whereby the locking element **258** is moved out of contact with the regulator wheel, and the sequence continues in the same manner as described above.

Auto-Stop Function

As described earlier, the second arm **268***b* of the auto-stop mechanism **260** is resting against the plunger rod segments **74** in the magazine. However, when the injection sequence is about to end when the medicament container has been emptied, there will be a space under the plunger rod follower **98**, which has been moved upwards during the "building" of the plunger rod. Thus the second arm **268***b* is moved out of contact and the force of the torsion spring **270** will cause the beam **262** to turn around its shaft **264**, whereby the first arm **268***a* will act on the ledge **206** of the needle cover **188**, FIG. **24**. This will in turn cause the needle cover **208** to be turned around its longitudinal axis, which coincides with the proximal-distal axis **14**.

The turning of the needle cover **188** will further cause the arms **180** of the needle holder **182** to be moved from the first part **204***a* of the slit to the third part **204***c* of the slit via the second part **204***b*, FIGS. **12** and **25**. The turning of the needle cover **188** will cause the ribs **190** on the outer surface of the needle cover to be aligned with the cut-outs **196**, FIG. **24** and due to the force of the needle cover spring **211** the needle cover **188** is urged in the proximal direction. When now the device is removed from the body of the patient, the needle cover **188** will extend and surround the needle cover **188**, FIG. **26**. The movement of the needle cover **188** is stopped when the ledges **206** come in contact with the inner surface of the proximal housing part **10**.

When in this position, the ledges **210** of the arms **208** on the inner surface of the proximal housing part **10** will engage the distal end surface of the needle cover **188**, preventing any movement of the needle cover **188** in the distal direction, thus locking the needle cover **188** in relation to the housing and the injection needle. Further, one of the ledges **206** is moved in contact with the teeth of the escapement wheel **240**, FIG. **27**, thereby preventing any further action or movement of the injection speed control mechanism **212**, should a user be pressing on the activation buttons. Thus the device is locked and ready to be discarded.

Manual Stop Function

Instead of the automatic stopping of the device, it may be stopped manually by a user. This is done by pressing the actuator element **278** upwards on the distal side of the device. This causes the arm **282** to slide vertically upwards,

whereby the beam **286** is also moved upwards. This upwards movement of the beam will cause the needle cover **188** to rotate due to the contact between the beam **286** and the ledge **207**, which rotation performs exactly the same functional sequence as with the automatic stop function, FIG. **28**. Thus the needle cover **188** will be extended and locked in the extended position and the injection speed control mechanism **212** will be locked by the interaction of the ledge **206** with the escapement wheel **240**. The device may now be removed and discarded.

It is to be understood that the embodiment described above and shown in the drawings is to be regarded only as a non-limiting example of the invention and that it may be modified in many ways within the scope of the patent claims.

The invention claimed is:

1. A medicament delivery device, comprising:

a housing;

a compartment in the housing for positioning a medicament container;

an injection needle arranged to the housing and connectable to the medicament container for supplying a dose of medicament;

a manually operated an activation mechanism for activating the device;

an actuation mechanism operably connected to the activation mechanism and configured to move and extend the injection needle from a first position inside the housing to a second position for penetration of a patient upon activation of the activation mechanism;

a plunger rod positioned within the housing to act on the medicament container during delivery of the dose of medicament through the injection needle, where movement of plunger rod is in a direction transverse to a movement of the injection needle from the first position to the second position;

a driver configured to act on the plunger rod for delivering the dose of medicament; and

a needle cover moveable relative to the injection needle and operably arranged in the housing between a position inside the housing and an extended position outside the housing for shielding the injection needle when the medicament container has been emptied.

2. The medicament delivery device of claim **1**, wherein the actuation mechanism further comprises a linkage configured to lock the injection needle in the second position.

3. The medicament delivery device of claim **2**, wherein the housing has an inner surface comprising a ledge that engages the needle cover to lock the needle cover in the extended position.

4. The medicament delivery device of claim **3**, wherein the activation mechanism comprises two operating elements disposed on opposite sides of the medicament delivery device.

5. The medicament delivery device of claim **4**, wherein the two operating elements comprise activation buttons that are manually depressed for activating the device.

6. The medicament delivery device of claim **5**, wherein the activation buttons are connected to the injection needle via a linkage included in the actuation mechanism, thereby enabling movement of the injection needle to the extended position when the activation buttons are depressed.

7. The medicament delivery device of claim **6**, wherein the linkage comprises a holding element.

8. The medicament delivery device of claim **1**, further comprising an injection speed control mechanism operatively connected to the driver.

9. The medicament delivery device of claim **8**, wherein the injection speed control mechanism comprises a balance wheel that interacts with a pallet fork that acts on an escapement wheel, and a transmission between the driver and the escapement wheel.

10. The medicament delivery device of claim **9**, further comprising a balance spring drivably connected to the escapement wheel.

11. The medicament delivery device of claim **8**, further comprising an auto-stop mechanism configured to stop the driver or the injection speed control mechanism at conclusion of a dose delivery sequence.

12. The medicament delivery device of claim **8**, further comprising a manually operable stop mechanism configured to stop the driver or the injection speed control mechanism upon activation.

13. The medicament delivery device of claim **8**, further comprising a manually operated pausing mechanism configured to stop and start the driver or the injection speed control mechanism upon activation.

14. The medicament delivery device of claim **12**, further comprising a medicament container penetration mechanism operably connected to the activation mechanism and configured to cause, upon activation, a communication between medicament inside the medicament container and the injection needle.

15. The medicament delivery device of claim **1**, wherein the plunger rod comprises a number of segments that are inter-connectable to each other.

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